AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
RUC RECOMMENDATIONS FOR
CMS REQUESTS

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CMS Request/Relativity Assessment Identified Codes

AMA
AMERICAN MEDICAL ASSOCIATION

ama-assn.org
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March 21, 2014

Marilyn B. Tavenner
Administrator
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: RUC Recommendations

Dear Ms. Tavenner:

The American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) submits the enclosed recommendations for work relative values and direct practice expense inputs to the Centers for Medicare and Medicaid Services (CMS). These recommendations relate to existing services identified by the RUC's Relativity Assessment Workgroup and CMS for the 2015 Medicare Physician Payment Schedule.

The enclosed recommendations result from the RUC's review of physicians' services from the January 29 – Feb 1, 2014, meeting and include the following issues for consideration:

- Hormone Pellet Implantation (11980)
- Injection for Knee Arthrography (27370)
- Endobronchial Ultrasound (31620)
- Bronchoscopy-Computer Assisted (31627)- PE Only
- Percutaneous Implantation of Neuroelectrodes (64561)
- X-Ray Exams (71100, 72070, 73060, 73565, 73590, 73600) – *Postponed until Sept 2014*
- CT Angiography-Chest (71275)
- Swallowing Function (74230)
- Microdissection (88380, 88381)
- Doppler Echocardiography (93320, 93321, 93325)
- Continuous Glucose Monitoring (95250, 95251)
- Electronic Analysis of Implanted Neurostimulator Pulse Generator System (95971, 95972)
- Hyperbaric Oxygen Therapy (99183)
- Laparoscopic Hysterectomy (58541-58544, 58570-58573) – *Postponed until April 2014*

Practice Expense Recommendations

The RUC Practice Expense Subcommittee is submitting recommendations from the Practice Expense Subcommittee Moderate Sedation Monitoring Time Workgroup and recommended changes to the moderate sedation standard package. In addition we are submitting recommendations from past RUC meetings that CMS has not yet addressed in rulemaking. Attached to this letter we are submitting the following final recommendations of the RUC Practice Expense Subcommittee:

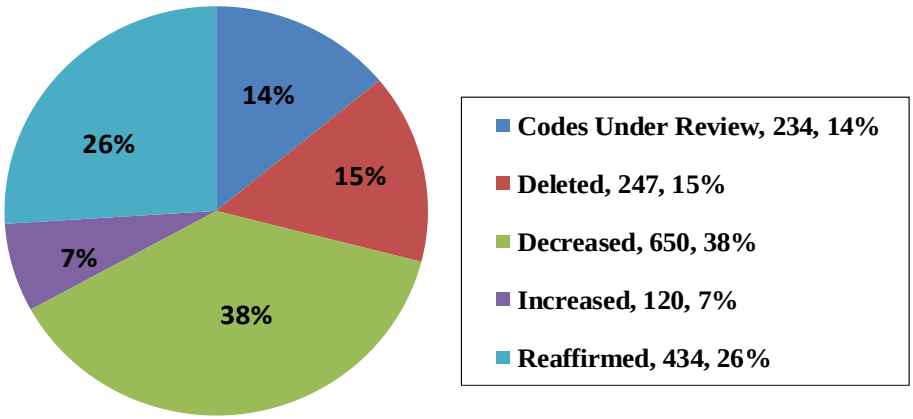
- **Moderate Sedation Monitoring Time Workgroup** - The Workgroup was charged with reviewing practice expense clinical staff time for monitoring following moderate sedation in the non-facility setting. Prior to the April 2013 RUC meeting, the standard for the assignment of post-service monitoring time following moderate sedation is 15 minutes of RN time for every hour of monitoring. However, due to requests from specialty societies for additional time above the standard for post-service RN monitoring time, the PE Subcommittee created a workgroup to review the practice expense clinical staff time for monitoring following moderate sedation in the non-facility setting. To identify these services, AMA staff reviewed the Summary of CPT Codes That Include Moderate (Conscious) Sedation (Appendix G in the CPT book). Out of the 389 codes on Appendix G, 163 were identified as having monitoring time following moderate sedation in the non-facility setting, with monitoring times ranging from 6 to 60 minutes. The majority of codes with inherent moderate sedation, 101 of 163, had 1 hour of post procedure monitoring (15 minutes of RN time). The Workgroup determined that the 46 codes with monitoring time of 60 minutes and the additional 16 codes with times other than the standard 15 minutes should be reviewed by the dominant specialty provider. The Workgroup also reviewed the appropriate staff type for the post procedure monitoring time. Along with the recommendation and workgroup reports, clinical practice guidelines and published literature provided by the specialty societies, as well as a letter of support from the American Nurses Association (ANA), are included with this submission.
- **Moderate Sedation Standard Package -** Currently the moderate sedation standard package does not include a stretcher (sometimes refer to as a gurney). Many specialty societies that perform procedures with moderate sedation have indicated that a stretcher is needed and include it as a separate equipment direct PE input in their recommendations to the PE Subcommittee. The PE Subcommittee recommendation for changes to the moderate sedation standard package is included with this submission.
- **Contrast Imaging Workgroup -** The Workgroup developed a list of supplies that are routinely used in enhanced contrast imaging services. In addition, the Workgroup agreed to add to the IV Starter Kit an underpad 2ft x 3ft (Chux) (SB044). The recommendations of the Workgroup were reviewed and accepted by the Practice Expense Subcommittee at the October 2013 RUC Meeting and were originally submitted CMS in November 2013.
- **Endoscope Cleaning and Disinfecting Pack, SA042 -** In January 2012, the PE Subcommittee noted that a basin is missing from the Endoscope Cleaning and Disinfecting Pack, CMS supply item SA042. The recommendations of the Workgroup were reviewed and accepted by the Practice Expense Subcommittee at the January 2012 RUC Meeting and originally submitted to CMS in May 2012.

RUC Progress in Identifying and Reviewing Potentially Misvalued Codes

Since 2006, the RUC has identified 1,685 potentially misvalued services through objective screening criteria and has completed review of 1,451of these services. The RUC has recommended that over half of the services identified be decreased or deleted (Table 1).

Table 1.

RUC Potentially Misvalued Services Project by Total Number of Codes in Project (1,685)



SOURCE: AMERICAN MEDICAL ASSOCIATION

The RUC has worked vigorously over the past several years to identify and address misvaluations in the RBRVS through provision of revised physician time data and resource cost recommendations to CMS. The RUC looks forward to working with CMS on a concerted effort to address potentially misvalued services. A detailed report of the RUC's progress is appended to this letter.

CPT Codes 77001-77003 - Final Rule for CY 2014

As detailed in the CY 2013 final rule with comment period, CPT codes 77001, 77002 and 77003 were assigned CY 2013 interim final work RVUs of 0.38, 0.54 and 0.60, respectively, based upon AMA RUC recommendations. CMS agreed with the AMA RUC-recommended values but were concerned that the recommended intra-service times for all three codes are generally higher than the procedure codes with which they are typically billed. For example, CPT code 77002 has 15 minutes of intra-service time and CPT code 20610 has an intra-service time of only 5 minutes. CMS requested additional public comment and input from the AMA RUC and other stakeholders regarding the appropriate relationship between the intra-service time associated with fluoroscopic guidance and the intra-service time of the procedure codes with which they are typically billed.

In January 2014, the specialty societies indicated and the RUC agreed that there is no clinical reason why the fluoroscopic guidance should be shorter than the associated procedure. Imaging guidance may take more time than the procedure, for example, when it is difficult to place a needle precisely for a short procedure. Additionally, imaging guidance may be longer because the guidance necessary to advance the needle adjacent to a tendon sheath or epidural space takes longer than the subsequent intervention itself. The procedure service only measures the skin to skin procedure time. **The RUC recommends that the times and values for these recently reviewed services, codes 77001-77003, are appropriate and no further action is necessary. The RUC also noted that CPT code 20610, which CMS specifically queried in the Final Rule, has already been identified and a new code to bundle this service with fluoroscopic guidance has been created and a RUC recommendation will be submitted to CMS in May 2014.**

Moderate Sedation Performed by another Provider the Same Day Analysis

For review at the January 2014 RUC meeting, the RUC requested that CMS provide data for each procedure in Appendix G (CPT Codes that include Moderate (Conscious) Sedation), to determine the frequency for conscious or other sedation performed by another provider the same day. These data would allow the Relativity Assessment Workgroup to identify services for which moderate sedation may not be typical and the resource inputs assumed by the RUC may be incorrect.

Since the RUC has not received the data request from CMS from the 100% Medicare Claims file, the Relativity Assessment Workgroup analyzed Appendix G with an enhanced version of the Medicare Claims 5% file. These data show the percentage of anesthesia services that are performed by different provider on the same patient/same day. These data indicate that another provider is typically reporting an anesthesia service for approximately 86 services in Appendix G. The Workgroup discussed that reporting anesthesia services when the work and direct practice expense inputs for moderate sedation are already included in these services is problematic and Medicare and other payers. *Please see the attached spreadsheet for Moderate Sedation Performed by a Different Provider on the Same Day from the 5% Medicare Claims file.* **The RUC requests that CMS provide the frequency of sedation services provided by another physician on the same patient/same day for the facility and non-facility setting for services on the Appendix G list from the 100% Medicare claims file. The RUC is in the process of forming a CPT/RUC Moderate Sedation Ad Hoc Workgroup to review these data.**

BETOS Workgroup Review Progress

Recently, the RUC created an ad hoc Workgroup to review the Berenson-Eggers Type of Service (BETOS) classification system. This Workgroup was prompted by a letter from the American College of Surgeons that raised concerns about the current BETOS classifications and code assignments. The BETOS Workgroup, along with helpful work from the specialty societies, have undergone a review of the current problems with BETOS and discussed several improvements to the BETOS system, and acknowledged that CMS owns and maintains BETOS. Therefore, the RUC would like to take this opportunity to inform CMS of the Workgroup's discussions and ask for the Agency's feedback and guidance prior to continuing a further review. **Specifically, we would like to ask the Agency's opinion on the value of such a review, feedback on the work to date, and for guidance on future areas to review. Also, due to the broad use of BETOS as a research tool, we would like to inquire about the possibility of CMS requesting stakeholder input regarding a revision of the BETOS product.** Attached to these recommendations is a letter detailing the Workgroup's progress and requests.

Pre-Service Time Standards

In January 2014, the RUC acknowledged that several items in the pre-service time packages were not described clearly. Specifically, it was noted that there are a limited number of RUC surveyed codes with Package 6 that include moderate sedation. By allocating the five minutes of time from (C) administer local anesthesia to (A) administer moderate sedation, Package 6 would no longer be applicable as written to account for prolonged local and/or topical anesthetic treatments that were formerly categorized as Package 6. Therefore, the RUC revised the following: 1) Re-allocate five minutes back from (A) administer moderate sedation to (C) administer local anesthetic; 2) Rename Package 5 to "Procedure with Minimal Anesthesia Care (If no anesthesia care deduct 1 minute)"; 3) Differentiate Package 6 to Package 6A "Procedure with local/topical anesthesia care requiring wait time for anesthesia to take effect" and Package 6B "Procedure with sedation"; and 4) Add a footnote to Package 5 instructing removal of 1 minute if no anesthetic is applied. The following is a list of the pre-service time packages and total pre-service times:

Pre-Service Time Standards:

Package	Description	Pre-Service Evaluation (Min)	Pre-Service Positioning (Min)	Pre-Service Scrub, Dress and Wait (Min)
Facility Setting				
Package 1A	Straightforward Patient/Straightforward Procedure (No sedation/anesthesia care)	13	1	6
Package 1B*	Straightforward Patient/Straightforward Procedure (With sedation/anesthesia care)	19	1	5
Package 2A	Difficult Patient/Straightforward Procedure (No sedation/anesthesia care)	18	1	6
Package 2B*	Difficult Patient/Straightforward Procedure (With sedation/anesthesia care)	33	1	5
Package 3	Straightforward Patient/Difficult Procedure	33	3	15
Package 4	Difficult Patient/Difficult Procedure	40	3	20
Non-Facility Setting				
Package 5**	Procedure with minimal anesthesia care (If no anesthesia care deduct 1 minute)	7	0	1
Package 6A	Procedure with local/topical anesthesia care requiring wait time for anesthesia to take effect	17	1	5
Package 6B*	Procedure with sedation	22	1	0

*Indicates packages that contain moderate sedation
**If the procedure does not require local anesthesia, 1 minute should be removed from pre-service time

Post-Service Time Standards

In January 2014, the RUC made revisions to the standard post-service time packages. The following is a list of the post-service time packages and total times:

Package 7A (Local Anesthesia/Straightforward Procedure)	18 minutes
Package 7B (Local Anesthesia/Complex Procedure)	21 minutes
Package 8A (IV Sedation/Straightforward Procedure)	25 minutes
Package 8B (IV Sedation/Complex Procedure)	28 minutes
Package 9A (General Anesthesia or Complex Regional Block/Straightforward Procedure)	30 minutes
Package 9B (General Anesthesia or Complex Regional Block/Complex Procedure)	33 minutes

Enclosed are the revised versions of both the pre and post time packages.

We appreciate your consideration of these RUC recommendations. If you have any questions regarding the attached materials, please contact Sherry Smith at (312) 464-5604.

Sincerely,

Barbara Levy MD

Barbara Levy, MD

Enclosures

cc: Kathy Bryant
Jessica Bruton
Edith Hambrick, MD
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Ryan Howe
RUC Participants

Conscious/Moderate Sedation - 2011 carrier SAF

occur = number of unique occurrences of the reference CPT code by patient, date of service, provider (NPI #)

same provider = number times an anesthesia service was provided to same patient on the same day by same provider

different provider = number of times an anesthesia service was provided to same patient on the same day by different provider

Anesthesia service defined as CPT 00100-01999 and 99143-99150

		Same Day Anesthesia Service					
		CPT 00100-01999			CPT 99143-99150		
Reference CPT code	# Occur from 5% file	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider
10030	1	0	0	0%	0	0	0%
19298	4	0	0	0%	0	0	0%
20982	7	0	4	57%	0	0	0%
22520	453	0	127	28%	0	0	0%
22521	492	0	114	23%	0	1	0%
22522	175	0	47	27%	0	0	0%
22526	1	0	0	0%	0	0	0%
22527	1	0	0	0%	0	0	0%
31615	667	0	61	9%	0	0	0%
31620	719	0	371	52%	0	2	0%
31622	4109	7	1478	36%	0	4	0%
31623	1303	0	279	21%	0	0	0%
31624	4389	0	799	18%	0	7	0%
31625	1344	0	407	30%	0	1	0%
31626	50	0	37	74%	0	0	0%
31627	154	0	108	70%	0	0	0%
31628	1913	0	500	26%	1	0	0%
31629	1021	0	410	40%	0	2	0%
31634	4	0	1	25%	0	0	0%
31635	128	0	46	36%	0	0	0%
31646	235	0	13	6%	0	0	0%
31647	1	0	0	0%	0	0	0%
31648	1	0	0	0%	0	0	0%
31649	1	0	0	0%	0	0	0%
31651	1	0	0	0%	0	0	0%
31660	1	0	0	0%	0	0	0%
31661	1	0	0	0%	0	0	0%
31725	21	8	2	10%	0	0	0%
32201	12	0	0	0%	0	0	0%
32405	3079	0	78	3%	912	0	0%
32550	469	0	199	42%	0	1	0%
32551	3103	1	382	12%	8	9	0%
32553	99	0	6	6%	0	1	1%
33010	210	0	30	14%	0	0	0%
33011	4	0	1	25%	0	0	0%
33206	57	0	15	26%	0	0	0%
33207	1154	0	342	30%	0	0	0%
33208	5944	0	1651	28%	0	0	0%
33210	1149	2	143	12%	0	2	0%
33211	35	0	5	14%	0	0	0%
33212	546	0	148	27%	0	0	0%
33213	2389	0	596	25%	0	0	0%
33214	33	0	16	48%	0	0	0%
33216	277	0	109	39%	0	0	0%
33217	116	0	41	35%	0	0	0%
33218	37	0	15	41%	0	0	0%
33220	28	0	12	43%	0	0	0%
33221	1	0	0	0%	0	0	0%
33222	284	0	96	34%	0	0	0%
33223	322	0	170	53%	0	0	0%
33227	1	0	0	0%	0	0	0%
33228	1	0	0	0%	0	0	0%
33229	1	0	0	0%	0	0	0%
33230	1	0	0	0%	0	0	0%
33231	1	0	0	0%	0	0	0%
33233	3134	0	849	27%	0	0	0%
33234	188	0	90	48%	0	0	0%
33235	184	0	98	53%	0	0	0%
33240	1832	0	809	44%	0	1	0%
33241	2239	0	1015	45%	0	1	0%

		Same Day Anesthesia Service					
		CPT 00100-01999			CPT 99143-99150		
Reference CPT code	# Occur from 5% file	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider
33244	294	0	173	59%	0	0	0%
33249	2688	0	1256	47%	0	0	0%
33262	1	0	0	0%	0	0	0%
33263	1	0	0	0%	0	0	0%
33264	1	0	0	0%	0	0	0%
33990	1	0	0	0%	0	0	0%
33991	1	0	0	0%	0	0	0%
33992	1	0	0	0%	0	0	0%
33993	1	0	0	0%	0	0	0%
35471	411	0	55	13%	0	0	0%
35472	45	0	19	42%	0	0	0%
35475	2051	0	223	11%	2	0	0%
35476	11888	0	1364	11%	3	0	0%
36010	3591	1	725	20%	301	2	0%
36140	1117	7	320	29%	37	0	0%
36147	14800	0	1658	11%	4	0	0%
36148	3422	0	302	9%	2	0	0%
36200	3021	4	1379	46%	154	2	0%
36221	1	0	0	0%	0	0	0%
36222	1	0	0	0%	0	0	0%
36223	1	0	0	0%	0	0	0%
36224	1	0	0	0%	0	0	0%
36225	1	0	0	0%	0	0	0%
36226	1	0	0	0%	0	0	0%
36227	1	0	0	0%	0	0	0%
36228	1	0	0	0%	0	0	0%
36245	3834	1	464	12%	394	2	0%
36246	2031	0	353	17%	243	1	0%
36247	2831	0	497	18%	462	1	0%
36248	709	0	123	17%	191	1	0%
36251	1	0	0	0%	0	0	0%
36252	1	0	0	0%	0	0	0%
36253	1	0	0	0%	0	0	0%
36254	1	0	0	0%	0	0	0%
36481	45	1	13	29%	0	0	0%
36555	5	2	2	40%	0	0	0%
36557	6	0	6	100%	0	0	0%
36558	6834	8	1937	28%	2	2	0%
36560	4	0	2	50%	0	0	0%
36561	6322	12	3627	57%	0	4	0%
36563	62	0	53	85%	0	0	0%
36565	224	2	175	78%	0	0	0%
36566	49	2	19	39%	0	0	0%
36568	1	0	0	0%	0	0	0%
36570	1	0	0	0%	0	0	0%
36571	442	1	273	62%	0	1	0%
36576	27	0	13	48%	0	0	0%
36578	27	0	12	44%	0	0	0%
36581	2206	0	291	13%	0	1	0%
36582	82	0	36	44%	0	0	0%
36583	3	0	3	100%	0	0	0%
36585	6	0	3	50%	0	0	0%
36590	2417	0	911	38%	0	0	0%
36870	3067	0	268	9%	2	0	0%
37183	31	0	8	26%	0	0	0%
37184	365	0	123	34%	0	1	0%
37185	93	0	37	40%	0	1	1%
37186	95	0	13	14%	0	0	0%
37187	263	0	40	15%	0	0	0%
37188	18	0	1	6%	0	0	0%
37191	1	0	0	0%	0	0	0%
37192	1	0	0	0%	0	0	0%
37193	1	0	0	0%	0	0	0%
37197	1	0	0	0%	0	0	0%
37210	20	0	1	5%	0	0	0%

		Same Day Anesthesia Service					
		CPT 00100-01999			CPT 99143-99150		
Reference CPT code	# Occur from 5% file	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider
37211	1	0	0	0%	0	0	0%
37212	1	0	0	0%	0	0	0%
37213	1	0	0	0%	0	0	0%
37214	1	0	0	0%	0	0	0%
37215	431	0	78	18%	0	1	0%
37216	1	0	0	0%	0	0	0%
37220	548	1	176	32%	0	0	0%
37221	1576	0	386	24%	0	0	0%
37222	157	0	55	35%	0	0	0%
37223	280	0	74	26%	0	0	0%
37224	1534	0	383	25%	2	0	0%
37225	1144	0	185	16%	0	0	0%
37226	1615	0	395	24%	1	0	0%
37227	475	0	90	19%	0	0	0%
37228	1119	0	281	25%	0	0	0%
37229	618	0	107	17%	0	0	0%
37230	195	0	45	23%	0	0	0%
37231	73	0	8	11%	1	0	0%
37232	320	0	81	25%	0	0	0%
37233	129	0	28	22%	0	0	0%
37234	33	0	8	24%	0	0	0%
37235	10	0	2	20%	0	0	0%
37236	1	0	0	0%	0	0	0%
37237	1	0	0	0%	0	0	0%
37238	1	0	0	0%	0	0	0%
37239	1	0	0	0%	0	0	0%
37241	1	0	0	0%	0	0	0%
37242	1	0	0	0%	0	0	0%
37243	1	0	0	0%	0	0	0%
37244	1	0	0	0%	0	0	0%
43200	708	0	482	68%	0	0	0%
43201	22	0	18	82%	0	0	0%
43202	181	0	96	53%	0	0	0%
43204	3	0	2	67%	0	0	0%
43205	20	0	9	45%	0	0	0%
43206	1	0	0	0%	0	0	0%
43211	1	0	0	0%	0	0	0%
43212	1	0	0	0%	0	0	0%
43213	1	0	0	0%	0	0	0%
43214	1	0	0	0%	0	0	0%
43215	85	0	42	49%	0	1	1%
43216	4	0	2	50%	0	0	0%
43217	9	0	5	56%	0	0	0%
43219	25	0	21	84%	0	0	0%
43220	155	0	88	57%	0	0	0%
43226	129	0	84	65%	0	0	0%
43227	27	0	11	41%	0	0	0%
43228	228	0	181	79%	0	0	0%
43229	1	0	0	0%	0	0	0%
43231	31	0	24	77%	0	0	0%
43232	18	0	11	61%	0	0	0%
43233	1	0	0	0%	0	0	0%
43235	19806	0	8072	41%	0	11	0%
43236	771	0	414	54%	0	1	0%
43237	32	0	19	59%	0	0	0%
43238	35	0	22	63%	0	0	0%
43239	73101	0	38570	53%	0	11	0%
43240	28	0	24	86%	0	0	0%
43241	201	0	93	46%	0	0	0%
43242	1347	0	994	74%	0	1	0%
43243	95	0	45	47%	0	0	0%
43244	811	0	367	45%	0	0	0%
43245	635	0	320	50%	0	0	0%
43246	6234	0	3079	49%	0	0	0%
43247	1452	0	667	46%	0	3	0%

		Same Day Anesthesia Service					
		CPT 00100-01999			CPT 99143-99150		
Reference CPT code	# Occur from 5% file	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider
43248	5061	0	2506	50%	0	0	0%
43249	4615	0	2052	44%	0	0	0%
43250	283	0	149	53%	0	0	0%
43251	1309	0	732	56%	0	0	0%
43252	1	0	0	0%	0	0	0%
43253	1	0	0	0%	0	0	0%
43254	1	0	0	0%	0	0	0%
43255	2712	0	1093	40%	0	0	0%
43256	190	0	139	73%	0	0	0%
43257	6	0	6	100%	0	0	0%
43258	858	0	451	53%	0	1	0%
43259	1773	0	1221	69%	0	1	0%
43260	586	0	422	72%	0	5	1%
43261	428	0	321	75%	0	2	0%
43262	2960	0	2214	75%	0	4	0%
43263	34	0	25	74%	0	0	0%
43264	2372	0	1793	76%	0	1	0%
43265	159	0	128	81%	0	0	0%
43266	1	0	0	0%	0	0	0%
43267	10	0	9	90%	0	0	0%
43268	1833	0	1415	77%	0	6	0%
43269	1032	0	802	78%	0	1	0%
43270	1	0	0	0%	0	0	0%
43271	626	0	494	79%	0	0	0%
43272	15	0	11	73%	0	0	0%
43273	209	0	179	86%	0	0	0%
43274	1	0	0	0%	0	0	0%
43275	1	0	0	0%	0	0	0%
43276	1	0	0	0%	0	0	0%
43277	1	0	0	0%	0	0	0%
43278	1	0	0	0%	0	0	0%
43453	144	0	65	45%	0	0	0%
43456	98	0	52	53%	0	0	0%
43458	90	0	40	44%	0	0	0%
44360	279	0	162	58%	0	0	0%
44361	764	0	465	61%	0	0	0%
44363	6	0	5	83%	0	0	0%
44364	11	0	6	55%	0	0	0%
44365	6	0	4	67%	0	0	0%
44366	146	0	72	49%	0	0	0%
44369	73	0	50	68%	0	0	0%
44370	11	0	9	82%	0	0	0%
44372	57	0	24	42%	0	0	0%
44373	63	0	25	40%	0	0	0%
44376	117	0	62	53%	0	0	0%
44377	84	0	53	63%	0	0	0%
44378	44	0	37	84%	0	0	0%
44379	2	0	0	0%	0	0	0%
44380	101	0	47	47%	0	0	0%
44382	52	0	25	48%	0	0	0%
44383	6	0	3	50%	0	1	17%
44385	47	0	12	26%	0	0	0%
44386	42	0	22	52%	0	0	0%
44388	228	0	115	50%	0	0	0%
44389	82	0	38	46%	0	0	0%
44390	3	0	1	33%	0	0	0%
44391	15	0	6	40%	0	0	0%
44392	37	0	17	46%	0	0	0%
44393	14	0	5	36%	0	0	0%
44394	69	0	33	48%	0	0	0%
44397	1	0	0	0%	0	0	0%
44500	583	0	24	4%	0	0	0%
44901	16	0	2	13%	0	0	0%
45303	43	0	7	16%	0	0	0%
45305	58	0	19	33%	0	0	0%

		Same Day Anesthesia Service					
		CPT 00100-01999			CPT 99143-99150		
Reference CPT code	# Occur from 5% file	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider
45307	6	0	2	33%	0	0	0%
45308	3	0	1	33%	0	0	0%
45309	3	0	1	33%	0	0	0%
45315	18	0	4	22%	0	0	0%
45317	32	0	11	34%	0	1	3%
45320	7	0	1	14%	0	0	0%
45321	10	0	5	50%	0	0	0%
45327	1	0	1	100%	0	0	0%
45332	6	0	2	33%	0	0	0%
45333	84	0	28	33%	0	0	0%
45334	178	0	53	30%	0	0	0%
45335	141	0	55	39%	0	0	0%
45337	54	0	20	37%	0	1	2%
45338	226	0	80	35%	0	0	0%
45339	80	0	26	33%	0	0	0%
45340	52	0	15	29%	0	0	0%
45341	173	0	70	40%	0	0	0%
45342	20	0	8	40%	0	0	0%
45345	24	0	15	63%	0	0	0%
45355	49	0	33	67%	0	0	0%
45378	35595	0	18759	53%	1	5	0%
45379	43	0	22	51%	0	0	0%
45380	43667	0	22133	51%	0	2	0%
45381	3121	0	1559	50%	0	0	0%
45382	1111	0	481	43%	1	0	0%
45383	2776	0	1452	52%	0	0	0%
45384	8518	0	4767	56%	1	5	0%
45385	33613	0	15958	47%	1	1	0%
45386	97	0	46	47%	0	0	0%
45387	47	0	22	47%	0	0	0%
45391	36	0	15	42%	0	0	0%
45392	7	0	4	57%	0	0	0%
47000	2844	0	112	4%	708	2	0%
47011	153	0	4	3%	1	0	0%
47382	96	0	69	72%	0	0	0%
47525	487	0	30	6%	0	0	0%
48511	20	0	2	10%	0	0	0%
49021	1029	0	46	4%	0	1	0%
49041	51	0	3	6%	0	0	0%
49061	400	0	21	5%	1	0	0%
49405	1	0	0	0%	0	0	0%
49406	1	0	0	0%	0	0	0%
49407	1	0	0	0%	0	0	0%
49411	63	0	7	11%	0	0	0%
49418	141	0	17	12%	1	0	0%
49440	874	0	138	16%	0	0	0%
49441	54	0	13	24%	0	0	0%
49442	6	0	1	17%	0	0	0%
49446	231	0	18	8%	0	0	0%
50021	39	0	2	5%	0	0	0%
50200	1527	0	89	6%	0	3	0%
50382	42	0	7	17%	0	0	0%
50384	17	0	2	12%	0	0	0%
50385	16	0	12	75%	0	0	0%
50386	11	0	0	0%	0	0	0%
50387	247	0	13	5%	1	0	0%
50592	46	0	33	72%	0	0	0%
50593	69	0	41	59%	0	0	0%
57155	217	0	91	42%	0	0	0%
58823	15	0	2	13%	0	0	0%
66720	19	0	10	53%	0	0	0%
69300	1	0	0	0%	0	0	0%
77371	3	0	0	0%	0	0	0%
77600	215	0	0	0%	0	0	0%
77605	3	0	3	100%	0	0	0%

		Same Day Anesthesia Service					
		CPT 00100-01999			CPT 99143-99150		
Reference CPT code	# Occur from 5% file	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider
77610	1	0	0	0%	0	0	0%
77615	3	0	2	67%	0	0	0%
92920	1	0	0	0%	0	0	0%
92921	1	0	0	0%	0	0	0%
92924	1	0	0	0%	0	0	0%
92925	1	0	0	0%	0	0	0%
92928	1	0	0	0%	0	0	0%
92929	1	0	0	0%	0	0	0%
92933	1	0	0	0%	0	0	0%
92934	1	0	0	0%	0	0	0%
92937	1	0	0	0%	0	0	0%
92938	1	0	0	0%	0	0	0%
92941	1	0	0	0%	0	0	0%
92943	1	0	0	0%	0	0	0%
92944	1	0	0	0%	0	0	0%
92953	38	0	6	16%	0	0	0%
92960	7013	2	3473	50%	0	13	0%
92961	63	1	26	41%	0	0	0%
92973	770	0	16	2%	0	0	0%
92974	10	0	0	0%	0	0	0%
92975	37	0	0	0%	0	0	0%
92978	2219	0	38	2%	0	0	0%
92979	261	0	3	1%	0	0	0%
92986	138	0	17	12%	0	0	0%
92987	9	0	2	22%	0	0	0%
93312	12225	2259	3978	33%	2	7	0%
93313	1055	942	329	31%	0	0	0%
93314	1035	41	460	44%	0	0	0%
93315	120	9	36	30%	0	0	0%
93316	9	8	1	11%	0	0	0%
93317	43	0	13	30%	0	0	0%
93318	89	10	51	57%	0	0	0%
93451	1491	0	39	3%	0	3	0%
93452	978	0	26	3%	0	0	0%
93453	338	0	20	6%	0	0	0%
93454	4088	0	96	2%	0	0	0%
93455	1214	0	17	1%	0	0	0%
93456	477	0	13	3%	0	0	0%
93457	111	0	0	0%	0	0	0%
93458	28881	1	424	1%	1	6	0%
93459	7062	0	99	1%	0	0	0%
93460	4814	0	78	2%	0	1	0%
93461	1065	0	18	2%	0	0	0%
93462	688	0	478	69%	0	0	0%
93463	370	0	8	2%	0	0	0%
93464	29	0	1	3%	0	1	3%
93505	757	0	5	1%	0	2	0%
93530	5	0	1	20%	0	0	0%
93561	38	0	17	45%	0	0	0%
93562	18	0	0	0%	0	0	0%
93563	13	0	3	23%	0	0	0%
93564	3	0	0	0%	0	0	0%
93565	17	0	8	47%	0	0	0%
93566	136	0	11	8%	0	0	0%
93567	2943	0	67	2%	0	0	0%
93568	131	0	13	10%	0	0	0%
93571	1331	0	15	1%	0	0	0%
93572	192	0	0	0%	0	0	0%
93582	1	0	0	0%	0	0	0%
93583	1	0	0	0%	0	0	0%
93609	599	0	220	37%	0	0	0%
93613	1666	0	1010	61%	0	0	0%
93615	4	0	4	100%	0	0	0%
93616	2	2	2	100%	0	0	0%
93618	31	0	10	32%	0	0	0%

		Same Day Anesthesia Service					
		CPT 00100-01999			CPT 99143-99150		
Reference CPT code	# Occur from 5% file	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider	Same provider	Different provider	% Anesthesia Svc Performed by Diff Provider
93619	84	0	35	42%	0	0	0%
93620	2979	0	1435	48%	0	0	0%
93621	2098	0	1086	52%	0	0	0%
93622	212	0	147	69%	0	0	0%
93624	19	0	11	58%	0	0	0%
93640	170	0	68	40%	0	0	0%
93641	3360	0	1652	49%	0	0	0%
93642	360	0	174	48%	0	0	0%
93650	486	0	161	33%	0	0	0%
93653	1	0	0	0%	0	0	0%
93654	1	0	0	0%	0	0	0%
93655	1	0	0	0%	0	0	0%
93656	1	0	0	0%	0	0	0%
93657	1	0	0	0%	0	0	0%
94011	1	0	0	0%	0	0	0%
94012	1	0	0	0%	0	0	0%
94013	1	0	0	0%	0	0	0%

March 13, 2014

Ms. Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1600-FC
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: BETOS Code Assignment to CPT and HCPCS Codes

Dear Ms. Tavenner:

The American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) created an ad hoc Workgroup to review the Berenson-Eggers Type of Service (BETOS) classification system. This Workgroup was prompted by a letter from the American College of Surgeons that raised concerns about the current BETOS classifications and code assignment. The Workgroup discussed several improvements to the BETOS system, and acknowledged that CMS owns and maintains BETOS. Therefore, we would like to take this opportunity to inform CMS of our discussions and ask for the Agency's feedback and guidance prior to continuing our further review.

The BETOS classification system was developed in the late 1980's prior to publication of the first Medicare Physician Fee Schedule (PFS) and prior to development and assignment of Medicare types of service and global payment policies. It is our understanding the BETOS primarily has been used to analyze changes in physician services over time. In the last few years, the Urban Institute and MedPAC have both commented that BETOS code assignments contain errors. MedPAC has also stated that BETOS is out of date.[1]

The RUC BETOS Workgroup engaged in a stepwise approach to reviewing BETOS code assignments. Our first observation was that the primary BETOS categories do not match the Medicare type of service (TOS) categories for procedures and services.

Medicare TOS Categories	BETOS Categories
1 Medical care	1 Evaluation and Management
2 Surgery	2 Procedures
3 Consultation	3 Imaging
4 Diagnostic radiology	4 Tests
5 Diagnostic laboratory	5 Durable Medical Equipment
6 Therapeutic radiology	6 Other
7 Anesthesia	7 Exceptions/Unclassified
8 Assistant at surgery	
9 Other medical items or services	

[1] MedPAC. Report to the Congress. Medicare Payment Policy. March 2011.

We also noted that many codes are assigned to BETOS categories that are inconsistent with CPT and Medicare type of service categories. For example, CPT code 36200 *Introduction of catheter into the aorta* is assigned to BETOS category "Imaging." However, in the Medicare PFS, code 36200 has a surgical global period of 000-days and is assigned TOS "Surgery" as a procedure. In addition, CPT code 36200 is in the surgery section of the CPT manual.

The BETOS Workgroup also discussed Procedure Subcategories *ambulatory*, *major* and *minor*, and questioned the usefulness of these Subcategories for analyzing changes in physician services. Ambulatory procedures in the 1980's were presumably tied to office-based or same-day procedures. Due to technology changes, some procedures that now meet these criteria today are assigned instead to the Major or Minor Procedure Subcategory. Further, the specialty societies noted many irregularities in assignment of codes to the Major or Minor Subcategories. We question the need for these three Subcategories (ambulatory, major, minor*)* as useful for analyzing changes in physician services in today's practice environment.

We welcome the opportunity to further discuss the benefits and limitations of various approaches for revising the BETOS procedures category, and to share additional information and recommendations. Updating the BETOS procedures category will help maintain the validity of the BETOS coding system, will work to avoid inaccurate conclusions about the impact of new payment policies and volume trends, and could result in a more reliable and useful research and payment policy tool for the future.

Prior to committing to the additional work of a comprehensive review, we would like to ask the Agency's opinion on the value of such a review, feedback on the work to date, and for guidance on future areas to review. We also would like to inquire about the possibility of CMS requesting stakeholder input regarding a revision of the BETOS product. We look forward to continued discussion of the BETOS system.

Sincerely,

Barbara S. Levy, MD

cc: RUC Participants
Edith Hambrick, MD
Steve Phurrough, MD
Kathy Bryant
Chad Rubin, MD

RUC Recommendations for Existing Codes

CPT Code	Descriptor	RUC Recommendation	CMS/Other Source - Utilization over 250,000	CMS Fastest Growing	Harvard-Valued - Utilization over 100,000	High Volume Growth	MPC List	New Technology /New Services
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)	1.10				X		
27370	Injection procedure for knee arthrography	Editorial revision at CPT. Review claims data at RAW Sept 2017				X		
31620	Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])	1.50 and Refer to CPT for clarification				X		
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])	PE Inputs Only						X
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less;	Postponed Until Apr 2014						X
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	Postponed Until Apr 2014						X
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g;	Postponed Until Apr 2014						X
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	Postponed Until Apr 2014						X
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less;	Postponed Until Apr 2014						X
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	Postponed Until Apr 2014						X
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g;	Postponed Until Apr 2014						X
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	Postponed Until Apr 2014						X
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed	5.44		X		X		
71100	Radiologic examination, ribs, unilateral; 2 views	Postponed until Sept 2014	X					
72070	Radiologic examination, spine; thoracic, 2 views	Postponed until Sept 2014	X					
73060	Radiologic examination; humerus, minimum of 2 views	Postponed until Sept 2014	X					
73565	Radiologic examination, knee; both knees, standing, anteroposterior	Postponed until Sept 2014	X					
73590	Radiologic examination; tibia and fibula, 2 views	Postponed until Sept 2014	X					
73600	Radiologic examination, ankle; 2 views	Postponed until Sept 2014	X					
71275	Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.82		X			X	
74230	Swallowing function, with cineradiography/videoradiography	0.53	X					
88380	Microdissection (ie, sample preparation of microscopically identified target); laser capture	1.14						X
88381	Microdissection (ie, sample preparation of microscopically identified target); manual	0.53						X

RUC Recommendations for Existing Codes

CPT Code	Descriptor	RUC Recommendation	CMS/Other Source - Utilization over 250,000	CMS Fastest Growing	Harvard-Valued - Utilization over 100,000	High Volume Growth	MPC List	New Technology /New Services
93325	Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)	0.07	X					
93320	Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete	0.38	X					
93321	Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List separately in addition to codes for echocardiographic imaging)	0.15	X					
95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measureme	0.90 and Refer to CPT			X	X		
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measureme	0.78 and Refer to CPT			X	X		
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session	2.11	X					

Physician Time from RUC Meeting:

January 2014 (CPT 2015)

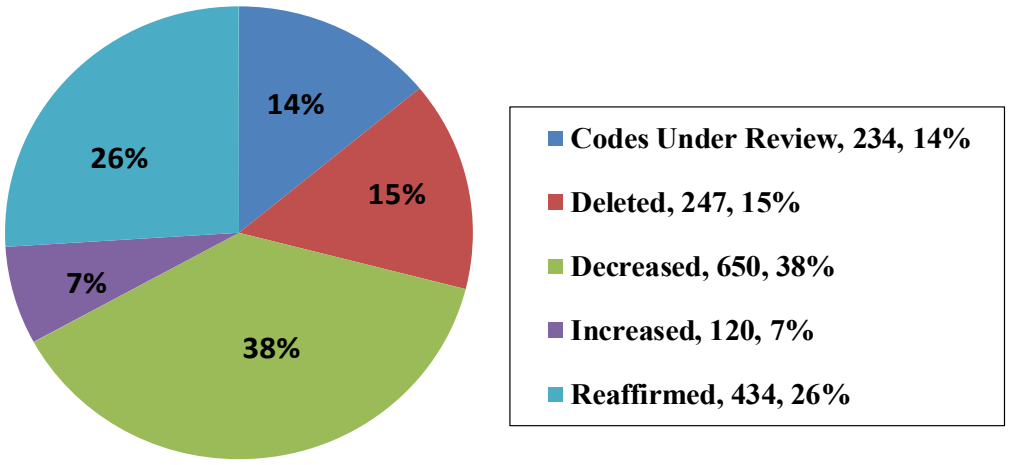
CPT Code	Pre-Service Evaluation	Pre-Service Positioning	Pre-Service Scrub Dress & Wait	Intra-Service	Immediate Post Service	99204	99211	99212	99213	99214	99215	99231	99232	99233	99238	99239	99291	99292	Total Time
11980	7	2	1	12	5														27
29200	7			9	2														18
29240	7			9	2														18
29260	7			9	2														18
29280	7			9	2														18
29520	7			9	2														18
29530	7			9	2														18
31620				40															40
64561	22	5		45	19					1									131
71275	5			25	5														35
74230	3			10	4														17
88380				33															33
88381				20															20
93320				15															15
93321				10															10
93325				10															10
95971	8			20	5														33
95972	8			23	5														36
99183	10			40	10														60

The RUC Relativity Assessment Workgroup Progress Report

In 2006, the RUC established the Five-Year Identification Workgroup (now referred to as the Relativity Assessment Workgroup) to identify potentially misvalued services using objective mechanisms for reevaluation prior to the next Five-Year Review. Since the inception of the Relativity Assessment Workgroup, the Workgroup and CMS have identified nearly 1,700 services through 15 different screening criteria for further review by the RUC. Additionally, the RUC charged the Workgroup with maintaining the "new technology" list of services that will be re-reviewed by the RUC as reporting and cost data become available.

To provide Medicare with reliable data on how physician work has changed over time, the Relative Value Scale Update Committee, with more than 300 experts in medicine and research, are examining nearly 1,700 potentially misvalued services accounting for $38 billion in Medicare spending. The update committee has recommended reductions to 650 services, redistributing more than $3 billion. Here are the outcomes for the committee's review of 1,685 codes:

Potentially Misvalued Services Project



SOURCE: AMERICAN MEDICAL ASSOCIATION

New Technology

As the RUC identifies new technology services that should be re-reviewed, a list of these services is maintained and forwarded to CMS. Currently, codes are identified as new technology based on recommendations from the appropriate specialty society and consensus among RUC members at the time of the RUC review for these services. RUC members consider several factors to evaluate potential new technology services, including: recent FDA-approval, newness or novelty of the service, use of an existing service in a new or novel way, and migration of the service from a Category III to Category I CPT code. The Relativity Assessment Workgroup maintains and develops all standards and procedures associated with the list, which contains 425 services. In September 2010, the re-review cycle began and since then the RUC has recommended 14 services to be re-examined. The remaining services are rarely performed (i.e., less than 500 times per year in the Medicare population) and will not be further examined. The Workgroup will continue to review the remaining 204 services every September after three years of Medicare claims data is available for each service.

Methodology Improvements
The RUC recently announced process improvements in the area of methodology following its October 2013 meetings. The process improvements are designed to strengthen the RUC's primary mission of providing the final RVS update recommendations to the Centers for Medicare and Medicaid Services.

In the area of methodology, the RUC is continuously improving its processes to ensure that it is best utilizing reliable, extant data. At its most recent meeting, the RUC increased the minimum number of respondents required for each survey of commonly performed codes:

- For services performed more than 1 million times per year in the Medicare population, at least 75 physicians must complete the survey.
- For services performed more than 100,000 annually, at least 50 physicians will be required.

Further strengthening its methodology, The RUC also announced that specialty societies will move to a centralized online survey process, which will be coordinated by the AMA and will utilize external expertise to ensure survey and reporting improvements.

Site of Service Anomalies
The Workgroup initiated its effort by reviewing services with anomalous sites of service when compared to Medicare utilization data. Specifically, these services are performed less than 50% of the time in the inpatient setting, yet include inpatient hospital Evaluation and Management services within their global period.

The RUC identified 194 services through the site of service anomaly screen. The RUC required the specialties to resurvey 129 services to capture the appropriate physician work involved. These services were reviewed by the RUC between April 2008 and February 2011. CMS implemented 124 of these recommendations in the 2009, 2010 and 2011 Medicare Physician Payment Schedules. The RUC submitted another five recommendations as well as re-reviewed and submitted 44 recommendations to previously reviewed site-of-service identified codes to CMS for the 2012 Medicare Physician Payment Schedule.

Of the remaining 65 services that were not re-surveyed, the RUC modified the discharge day management for 46 services, maintained three codes and removed two codes from the screen as the typical patient was not a Medicare beneficiary and would be an inpatient. The CPT Editorial Panel deleted 13 codes and the RUC will re-review one service in the CPT 2016 cycle. The RUC will reassess the data each year going forward to determine if any new site of service anomalies arise.

During this review, the RUC uncovered several services that are reported in the outpatient setting, yet, according to several expert panels and survey data from physicians who performed the procedure, the service, typically requires a hospital stay of greater than 23 hours. The RUC maintains that physician work that is typically performed, such as visits on the date of service and discharge work the following day, should be included within the overall valuation. Subsequent observation day visits and discharge day management service as appropriate proxies for this work.

High Volume Growth
The Workgroup assembled a list of all services with a total Medicare utilization of 1,000 or more that have increased by at least 100% from 2004 through 2006. The query initially resulted in the identification of 81 services, but was expanded by 15 services to include the family of services, totaling 96 services. Specialty societies submitted comments to the Workgroup in April 2008 to provide feedback or explanations for the growth in reporting. Following this review, the RUC required the specialties to survey 35 services to capture the appropriate work effort and/or practice expense inputs. These services were reviewed by the RUC between February 2009 and April 2010.

The RUC recommended removing 22 services from the screen as the volume growth did not impact the resources required to provide these services. The CPT Editorial Panel deleted 21 codes and will review another two services in the CPT 2015 cycle. In September 2011, the RUC began review of services after two years of utilization data were collected. The RUC submitted an additional 11 recommendations to CMS for services for the 2012-2015 Medicare Physician Payment Schedules. The RUC will continue to review the remaining five services after additional utilization data is collected.

In April 2013, the RUC assembled a list of all services with a total Medicare utilization of 10,000 or more that have increased by at least 100% from 2006 through 2011. The query resulted in the identification of 40 services and expanded to 48 services to include the appropriate family of services. The RUC recommended removing four services from the screen as the volume growth did not impact the resources required to provide these services. The RUC recommended ten services be referred to the CPT Editorial Panel for revision, six services be reviewed again after an additional two years of utilization data is collected and the remaining 28 services be surveyed for physician work and direct practice expense inputs for the 2015 CPT cycle.

CMS Fastest Growing
In 2008, CMS developed the Fastest Growing Screen to identify all services with growth of at least 10% per year over the course of three years from 2005-2007. Through this screen, CMS identified 114 fastest growing services and the RUC added 69 services to include the family of services, totaling 183. The RUC required the specialties to survey 72 services to capture the appropriate work effort and/or practice expense inputs. These services were reviewed by the RUC from February 2008 through April 2010 and submitted to CMS for the Medicare Physician Payment Schedule.

The RUC recommended removing 51 services from the screen as the volume growth did not impact the resources required to provide the service. The CPT Editorial Panel deleted 26 codes and will review another four services in the CPT 2016 cycle. The RUC submitted 25 recommendations to CMS for the 2012 -2015 Medicare Physician Payment Schedules. The RUC will review the remaining five services after additional utilization data is available.

High IWPUT
The Workgroup assembled a list of all services with a total Medicare utilization of 1,000 or more that have an intra-service work per unit of time (IWPUT) calculation greater than 0.14, indicating an outlier intensity. The query resulted in identification of 32 services. Specialty societies submitted comments to the Workgroup in April 2008 for these services. As a result of this screen, the RUC has reviewed and submitted recommendations to CMS for 28 codes, removing four services from the screen as the IWPUT was considered appropriate. The RUC completed review of services under this screen.

Services Surveyed by One Specialty – Now Performed by a Different Specialty
In October 2009, services that were originally surveyed by one specialty, but now performed predominantly by other specialties were identified and reviewed. The RUC identified 21 services by this screen, adding 19 services to address various families of codes. The majority of these services required clarification within CPT. The CPT Editorial Panel deleted 18 codes. The RUC submitted 22 recommendations for physician work and practice expense to CMS for the 2011-2014 Medicare Physician Payment Schedules. The RUC completed review of services under this screen.

In April 2013, the RUC queried the top two dominant specialties performing services based on Medicare utilization more than 1,000 and compared it to who originally surveyed the service. Two services were identified and the RUC recommended that one be removed from the screen since the specialty societies currently performing this service indicated that the service is appropriate and recommended that the other code be referred to CPT to be revised. The RUC completed review of services under this screen.

Harvard Valued

Utilization over 1 Million

CMS requested that the RUC pay specific attention to Harvard valued codes that have a high utilization. The RUC identified nine Harvard valued services with high utilization (performed over 1 million times per year). The RUC also incorporated an additional 12 Harvard valued codes within the initial family of services identified. The CPT Editorial Panel deleted one code. The RUC submitted 20 relative value work recommendations to CMS for the 2011 and 2012 Medicare Physician Payment Schedule. The RUC completed review of services under this screen.

Utilization over 100,000

The RUC continued to review Harvard-only valued codes with significant utilization. The Relativity Assessment Workgroup expanded the review of Harvard codes to those with utilization over 100,000 which totaled 38 services. The RUC expanded this screen by 101 codes to include the family of services, totaling 139 services. The CPT Editorial Panel deleted 27 codes. The RUC submitted 112 recommendations to CMS for the 2011-2014 Medicare Physician Payment Schedules. The RUC completed review of services under this screen.

Utilization over 30,000

In April 2011, the RUC continued to identify Harvard-only valued codes with utilization over 30,000, based on 2009 Medicare claims data. The RUC determined that the specialty societies should survey the remaining 36 Harvard codes with utilization over 30,000 for September 2011. The RUC expanded the screen to include the family of services, totaling 65 services. The CPT Editorial Panel deleted 12 codes. The RUC submitted recommendations for 53 services for the 2013-2014 Medicare Physician Payment Schedules. The RUC completed review of services under this screen.

Medicare Allowed Charges >$10 million

In June 2012, CMS identified 16 services that were Harvard-Valued with Annual Allowed Charges (2011 data) > $10 million. The RUC expanded this screen to 33 services to include the proper family of services. The RUC removed two services from review as the allowed charges are approximately $1 million and did not meet the screen criteria. The RUC submitted recommendations for 29 services for the 2013-2015 Medicare Physician Payment Schedules. The CPT Editorial Panel deleted one service. The RUC will review one remaining service after additional utilization data is available.

CMS/Other

Utilization over 500,000

In April 2011, the RUC identified 410 codes with a source of "CMS/Other." CMS/Other codes are services which were not reviewed by the Harvard studies or the RUC and were either gap filled, most often via crosswalk by CMS or were part of a radiology fee schedule. "CMS/Other" source codes would not have been flagged in the Harvard only screens, therefore the RUC recommended that a list of all CMS/Other codes be developed and reviewed. The RUC established the threshold for CMS/Other source codes with Medicare utilization of 500,000 or more, which resulted in 19 codes. The RUC expanded this screen to 21 services to include the proper family of services. The CPT Editorial Panel deleted one service and will review two services for CPT 2016. The RUC submitted recommendations for 16 services for the 2013-2015 Medicare Physician Payment Schedules. The RUC removed one service from the screen and will review one service after additional utilization data is available.

Utilization over 250,000
In April 2013, the RUC lowered the threshold to the CMS/Other source codes with Medicare utilization of 250,000 or more, which resulted in 26 services and was expanded to 38 services to include the family of services. The RUC referred eight services to the CPT Editorial Panel, will submit recommendations to CMS for 22 services for the Medicare Physician Payment Schedule and will review eight services after more utilization data is available.

Bundled CPT Services
Reported 95% or More Together
The Relativity Assessment Workgroup solicited data from CMS regarding services inherently performed by the same physician on the same date of service (95% of the time) in an attempt to identify pairings of services that should be bundled together. The CPT Editorial Panel deleted 31 individual component codes and replaced them with 53 new codes that describe bundles of services. The RUC then surveyed and reviewed work and practice costs associated with these services to account for any efficiencies achieved through the bundling. The RUC completed review of all services under this screen.

Reported 75% or More Together
In February 2010, the Workgroup continued review of services provided on the same day by the same provider, this time lowering the threshold to 75% or more together. The Relativity Assessment Workgroup again analyzed the Medicare claims data and found 151 code pairs which met the threshold. The Workgroup then collected these code pairs into similar "groups" to ensure that the entire family of services would be coordinated under one code bundling proposal. The grouping effort resulted in 20 code groups, totaling 80 codes, and were sent to specialty societies to solicit action plans for consideration at the April 2010 RUC meeting. Resulting from the Relativity Assessment Workgroup review, 81 additional codes were added for review as part of the family of services to ensure duplication of work and practice expense was mitigated throughout the entire set of services. Of the 161 total codes under review, the CPT Editorial Panel deleted 33 individual component codes and replaced the component coding with 127 new and/or revised codes that described the bundles of services. The CPT Editorial Panel and the RUC are currently working on one service and expect to complete this screen for final implementation in the 2016 Medicare Physician Payment Schedule.

Reported 75% or More Together – Part 2
In August 2011, the Joint CPT/RUC Workgroup on Codes Reported Together Frequently reconvened to perform its third cycle of analysis of code pairs reported together with 75% or greater frequency. The Workgroup reviewed 30 code pair Groups and recommended code bundling for 64 individual codes. In October 2012, the CPT Editorial Panel started review of code bundling solutions. Of the 99 total codes under review, the CPT Editorial Panel deleted 26 services and is scheduled to review 27 codes in the 2016 cycle. The RUC has submitted 46 code recommendations for the 2014-2015 Medicare Physician Payment Schedules.

Low Value/Billed in Multiple Units
CMS has requested that services with low work RVUs that are commonly billed with multiple units in a single encounter be reviewed. CMS identified services that are reported in multiples of five or more per day, with work RVUs of less than or equal to 0.50 RVUs.

In October 2010, the Workgroup reviewed 12 CMS identified services and determined that six of the codes were improperly identified as the services were either not reported in multiple units or were reported in a few units, but that was assumed in the original valuation. The RUC submitted recommendations for the remaining six services for the 2012 Medicare Physician Payment Schedule. The RUC completed review of services under this screen.

Low Value/High Volume Codes
CMS has requested that services with low work RVUs and high utilization be reviewed. CMS has requested that the RUC review 24 services that have low work RVUs (less than or equal to 0.25) and high utilization. The RUC questioned the criteria CMS used to identify these services as it appeared some codes were missing from the screen criteria indicated. The RUC identified codes with a work RVU ranging from 0.01 - 0.50 and Medicare utilization greater than one million. In February 2011, the RUC reviewed the codes identified by this criteria and added 5 codes, totaling 29. The RUC submitted 24 recommendations to CMS for the 2012 Medicare Physician Payment Schedule and five recommendations to CMS for the 2013 Medicare Physician Payment Schedule. The RUC completed review of services under this screen.

Multi-Specialty Points of Comparison List
CMS requested that services on the Multi-Specialty Points of Comparison (MPC) list should be reviewed. CMS prioritized the review of the MPC list to 33 codes, ranking the codes by allowed service units and charges based on CY 2009 claims data as well as those services reviewed by the RUC more than six years ago. The RUC expanded the list to 182 services to include additional codes as part of a family (over 100 codes of which are part of the review of GI endoscopy codes). The CPT Editorial Panel deleted 25 codes. The RUC submitted recommendations for 157 codes for the 2012-2015 Medicare Physician Payment Schedules. The RUC completed review of services under this screen.

CMS High Expenditure Procedural Codes
In the July 19, 2011, Proposed Rule for 2012, CMS requests that the RUC review a list of 70 high PFS expenditure procedural codes representing services furnished by an array of specialties. CMS selected these codes since they have not been reviewed for at least 6 years, and in many cases the last review occurred more than 10 years ago.

The RUC reviewed the 70 services identified and expanded the list to 128 services to include additional codes as part of the family. The CPT Editorial Panel deleted eight codes and will review five codes for the 2016 cycle. The RUC submitted 111 recommendations to CMS for the 2013-2015 Medicare Physician Payment Schedules will review utilization data for four services in 2015.

Services with Stand-Alone PE Procedure Time
In June 2012, CMS proposed adjustments to services with stand-alone procedure time assumptions used in developing non-facility PE RVUs. These assumptions are not based on physician time assumptions. CMS prioritized CPT codes that have annual Medicare allowed charges of $100,000 or more, include direct equipment inputs that amount to $100 or more, and have PE procedure times greater than five minutes for review. The RUC reviewed 27 services identified through this screen and expanded to 29 services to include additional codes as part of the family. The CPT Editorial Panel deleted 11 codes and will review one code for CPT 2016. The RUC submitted 17 recommendations for the 2014-2015 Medicare Physician Payment Schedules.

Pre-Time Analysis
In January 2014, the RUC reviewed codes that were RUC reviewed prior to April 2008, with pre-time greater than pre-time package 4 *Facility - Difficult Patient/Difficult Procedure* (63 minutes) for services with 2012 Medicare Utilization over 10,000. The screen identified 21 services with more pre-service time than the longest standardized pre-service package. The Relativity Assessment Workgroup reviewed these services and requests action plans from the specialty societies on how to address the pre-service time for these services. The Relativity Assessment Workgroup will review action plans at the April 2014 RUC meeting.

Post-Operative Visits

010-Day Global Codes

In January 2014, the RUC reviewed all 477, 010-day global codes to determine any outliers. Many 010-day global period services only include 1 post-operative office visit. The Relativity Assessment Workgroup pared down the list to 19 services with >1.5 office visits and 2012 Medicare utilization > 1,000. The Workgroup reviewed the 19 services and requests action plans from the specialty societies to address/explain the office visits associated with these services. The Relativity Assessment Workgroup will review action plans at the April 2014 RUC meeting.

090-Day Global Codes

In January 2014, the RUC reviewed all 3788, 090-day global codes to determine any outliers. Based on 2012 Medicare utilization data, 10 services were identified, that were reported at least 1,000 times per year and included more than six office visits. The Relativity Assessment Workgroup reviewed the 10 services and requests action plans from the specialty societies to address/explain the office visits associated with these services. The Relativity Assessment Workgroup will review action plans at the April 2014 RUC meeting.

Public Comment Requests

In 2011, CMS announced that due to the ongoing identification of potentially misvalued services by CMS and the RUC, the Agency will no longer conduct a separate Five-Year Review. CMS will now call for public comments on an annual basis as part of the comment process on the Final Rule each year.

Final Rule for 2013

In the Final Rule for the 2013 Medicare Physician Payment Schedule, the public and CMS identified 35 potentially misvalued services. The RUC reviewed these services and referred three services to the CPT Editorial Panel for revision. The RUC indicated they did not provide a recommendation for one service because it lacked specialty society interest. The RUC submitted recommendations for 20 services for the 2014 Medicare Physician Payment Schedule and will submit the remaining 11 recommendations for the 2015 cycle.

Final Rule for 2014

CMS did not receive any publicly nominated potentially misvalued codes for inclusion in the Proposed Rule for 2014. However, to broaden participation in the process of identifying potentially misvalued codes, CMS sought the input of Medicare contractor medical directors (CMDs). The CMDs have identified over a dozen services in which CMS is proposing as potentially misvalued. The RUC reviewed these services and appropriate families at the October 2013 RUC meeting and noted that two services identified were recently reviewed and recommendations were submitted for the 2014 Medicare Payment Schedule. The RUC recommended no further action for 10 services, deletion of one service, referral to the CPT Editorial Panel for eight services and to survey four services for the 2015 Medicare Payment Schedule.

Other Issues

In addition to the above screening criteria, the Relativity Assessment Workgroup performed an exhaustive search of the RUC database for services indicated by the RUC to be re-reviewed at a later date. Three codes were found that had not yet been re-reviewed. The RUC recommended a work RVU decrease for two codes and to maintain the work RVU for another code.

CMS also identified 72 services that required further practice expense review. The RUC submitted practice expense recommendations on 67 services and the CPT Editorial Panel deleted 5 services. The RUC also reviewed special requests for 19 audiology and speech-language pathology services. The RUC submitted recommendations for 10 services for the 2010 Medicare Physician Payment Schedule and the remaining nine services for the 2011 Medicare Physician Payment Schedule.

CMS Requests and RUC Relativity Assessment Workgroup Code Status

Total Number of Codes Identified*	**1,685**
Codes Completed	**1,451**
Work and PE Maintained	434
Work Increased	120
Work Decreased	531
Direct Practice Expense Revised (beyond work changes)	119
Deleted from CPT	247
Codes Under Review	**234**
Referred to CPT	55
RUC to Review April 2014	140
RUC future review after additional data obtained	39

**The total number of codes identified will not equal the number of codes from each screen as some codes have been identified in more than one screen.*

The RUC's efforts for 2009-2014 have resulted in $3 billion in redistribution within the Medicare Physician Payment Schedule.

Detailed Description of Pre-Service Time Packages (Minutes)

		FACILITY						NON-FAC		
		1A	1B*	2A	2B*	3	4	5**	6A	6B*
	Total Pre-Service Time	**20**	**25**	**25**	**39**	**51**	**63**	**8**	**23**	**23**
	CATEGORY SUBTOTALS									
A	Pre-Service Evaluation (IWPUT =0.0224)	13	19	18	33	33	40	7	17	22
B	Pre-Service Positioning (IWPUT = 0.0224)	1	1	1	1	3	3	0	1	1
C	Pre-Service Scrub, Dress and Wait (IWPUT =0.0081)	6	5	6	5	15	20	1	5	0
	DETAILS									
A	History and Exam (Performance and review of appropriate Pre-Tests)	5	5	10	10	10	15	4	9	9
A	Prepare for Procedure (Check labs, plan, assess risks, review procedure)	2	2	2	2	2	4	1	1	1
A	Communicate with patient and/or family (Discuss procedure/ obtain consent)	3	3	3	5	5	5	2	3	3
A	Communicate with other professionals	0	1	0	3	5	5	0	2	2
A	Check/set-up room, supplies and equipment	1	1	1	1	5	5	0	1	1
A	Check/ prepare patient readiness (Gown, drape, prep, mark)	1	1	1	1	5	5	0	1	1
A	Prepare/ review/ confirm procedure	1	1	1	1	1	1	0	0	0
A	Administer moderate sedation/observe (wait) anesthesia care	0	5	0	10	0	0	0	0	5
B	Perform/ supervise patient positioning	1	1	1	1	3	3	0	1	1
C	Administer local/topical anesthesia	1	0	1	0	0	0	1	5	0
C	Observe (wait anesthesia care)	0	0	0	0	10	15	0	0	0
C	Dress and scrub for procedure	5	5	5	5	5	5	0	0	0

* Indicates packages that contain moderate sedation
**If the procedure does not require local anesthesia, 1 minute should be removed from pre-service time

1A Straightforward Patient/Straightforward Procedure (No sedation/anesthesia care)
1B* Straightforward Patient/Straightforward Procedure (With sedation/anesthesia care)
2A Difficult Patient/Straightforward Procedure (No sedation/anesthesia care)
2B* Difficult Patient/Straightforward Procedure (With sedation/anesthesia care)
3 Straightforward Patient/Difficult Procedure
4 Difficult Patient/Difficult Procedure
5 Procedure with minimal anesthesia care (If no anesthesia care deduct 1 minute)
6A Procedure with local/topical anesthesia care requiring wait time for anesthesia to take effect
6B Procedure with sedation

Additional Positioning Times for Spinal Surgical Procedures

SS1	Anterior Neck Surgery (Supine) (eg ACDF)	15 Minutes
SS2	Posterior Neck Surgery (Prone) (eg laminectomy)	25 Minutes
SS3	Posterior Thoracic/Lumbar (Prone) (eg laminectomy)	15 Minutes
SS4	Lateral Thoracic/Lumbar (Lateral) (eg corpectomy)	25 Minutes
SS5	Anterior Lumbar (Supine) (eg ALIF)	15 Minutes
SS6	Dorsal Lithotomy	5 Minutes

Additional Positioning Times for Spinal Injection Procedures

SI1	Anterior Neck Injection (Supine) (eg discogram)	7 Minutes
SI2	Posterior Neck Injection (Prone) (eg facet)	5 Minutes
SI3	Posterior Thoracic/Lumbar (Prone) (eg epidural)	5 Minutes
SI4	Lateral Thoracic/Lumbar (Lateral) (eg discogram)	7 Minutes

Notes:

*Roll-over cells for additional detail where available

***Straightforward procedure: Integumentary, Non-incisional endoscopy, natural orifice**

*For building block IWPUT purposes whenever the procedure is on Appendix G – (Summary of CPT codes that include moderate (conscious) sedation) the IWPUT should be .0224 for the administration of moderate sedation line item because the physician is responsible for the administration of conscious sedation. If the procedure is one where conscious sedation is not inherent the same line item should have an IWPUT of .0081.

straightforward patient undergoing a straightforward procedure (Package 1B), if the procedure is performed under general anesthesia and the surveys support additional pre-service time.

Detailed Description of Facility Based Post-Service Time Packages (Minutes)						
	7A Local Anesthesia/ Straightforward Procedure	**7B Local Anesthesia/ Complex Procedure**	**8A IV Sedation/ Straightforward Procedure**	**8B IV Sedation/ Complex Procedure**	**9A General Anesthesia or Complex Regional Block/ Straightforward Procedure**	**9B General Anesthesia or Complex Regional Block/Complex Procedure**
Total Post-Service Time	**18**	**21**	**25**	**28**	**30**	**33**
Details:						
Application of Dressing[1]	2	2	2	2	2	2
Transfer of supine patient off table	1	1	1	1	1	1
Operative Note	5	5	5	5	5	5
Monitor patient recovery/ Stabilization	1	1	5	5	10	10
Communication with patient and/or family	5	5	5	5	5	5
Written post-operative note	2	5	2	5	2	5
Post-Operative Orders and Order Entry	2	2	5	5	5	5

Advisors may request additional time for circumstances that require additional work beyond the type of work described

1 This represents a simple dressing

AMA/Specialty Society RVS Update Committee Summary of Recommendations
High Volume Growth screen

January 2014

Hormone Pellet Implantation

At the October 2013, meeting the Relativity Assessment Workgroup reviewed High Volume Growth Services where Medicare utilization increased by at least 100% from 2006 to 2011. The RUC requested that these services be surveyed for physician work and develop practice expense inputs for the January 2014 RUC meeting. In January 2014 the RUC questioned whether CPT code 11981 should also be reviewed since it is "CMS/Other" and has not been reviewed. **The RUC requests the specialty societies submit an action plan to the RAW in April to consider whether 11981 is part of this family and should be surveyed.**

The RUC discussed the physician time and intensity associated with CPT Code 11980 *Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)* and the appropriate work RVU relative to similar services. The specialty societies indicated and the RUC agreed that 10 minutes of pre-service time, 12 minutes of intra-service time, and 5 minutes of post-service time, adequately accounts for the physician time required to perform this service. The RUC noted that the time has decreased since this code was last reviewed in February 2000 and acknowledged that the reduction in time may be a result of the creation of pre- and post-time packages. Based on this reduction in time, rather than maintain the current work RVU, the RUC recommended a direct crosswalk to CPT Code 11730 *Avulsion of nail plate, partial or complete, simple; single* (work RVU=1.10) with identical intra service time of 12 minutes and similar intensity. To further support the value the RUC compared the surveyed code to CPT Code 51705 *Change of cystostomy tube; simple* (work RVU= 0.90) and agreed that 11980 should be valued higher since this requires more physician work. The RUC also compared CPT Code 11980 to CPT Code 67810 *Incisional biopsy of eyelid skin including lid margin* (work RVU=1.18) and agreed that this procedure requires slightly more physician time and intensity, accounting for the higher work value. **The RUC recommends a work RVU of 1.10, a direct crosswalk to CPT code 11730 for CPT code 11980.**

Practice Expense
The RUC reviewed and approved the direct practice expense inputs with modifications as approved by the Practice Expense Subcommittee.

Work Neutrality
The RUC's recommendation for this code will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

CPT Code (•New)	CPT Descriptor	Global Period	Work RVU Recommendation
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)	000	1.10

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:11980 Tracking Number Original Specialty Recommended RVU: **1.48**
Presented Recommended RVU: **1.48**
Global Period: 000 RUC Recommended RVU: **1.10**

CPT Descriptor: Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 56 year old man has a diagnosis of hypogonadism, his serum testosterone is below the lower limit of the range of normal for testosterone. After discussion with his physician, he decides to undergo implantation of testosterone pellet(s).

Percentage of Survey Respondents who found Vignette to be Typical: 90%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: An explanation of the procedure is provided and informed consent is obtained. The patient is placed in either the supine, prone or Sim's position and the patient's skin is scrubbed with betadine followed by alcohol. After draping with sterile drapes, the abdominal skin area is anesthetized by raising a skin wheal with 10 cc 1% lidocaine.

Description of Intra-Service Work: A small incision is made into the skin with a scalpel and a trocar is inserted with a pellet implanter and the trocar is withdrawn. Forceps are used to place the hormone pellets in the external opening of the cannula and implant them 6 to 10 cm from the puncture wound with the blunt trocar into the subcutaneous area. Bleeding is controlled with a few minutes of pressure with sterile 4 x 4 gauze squares.

Description of Post-Service Work: A steri-strip is placed over the wound and additional dressing is held in place with non-allergic tape. The sterile bandage is left in place overnight.The patient is instructed to replace the bandage daily with band-aids until the puncture wound is completely closed. Dictate office notes. Provides patient with instructions

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014				
Presenter(s):	Thomas Turk, MD and Philip Wise, MD				
Specialty(s):	Urology				
CPT Code:	11980				
Sample Size:	82	**Resp N:**	44	**Response:** 53.6 %	
Description of Sample:	Random				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	1.00	10.00	**20.00**	42.50	500.00
Survey RVW:	1.19	1.69	**2.10**	2.60	4.50
Pre-Service Evaluation Time:			**13.50**		
Pre-Service Positioning Time:			**3.00**		
Pre-Service Scrub, Dress, Wait Time:			**5.00**		
Intra-Service Time:	5.00	10.00	**12.00**	15.00	20.00

Immediate Post Service-Time:	**5.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

5 - NF Procedure without sedation/anesthesia care

CPT Code:	11980	**Recommended Physician Work RVU: 1.10**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**7.00**	**7.00**	**0.00**
Pre-Service Positioning Time:		**2.00**	**0.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**1.00**	**1.00**	**0.00**
Intra-Service Time:		**12.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

7A Local/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**5.00**	**16.00**	**-11.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
55876	000	1.73	**RUC Time**

CPT Descriptor Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
10060	000	1.22	**RUC Time**	503,463

CPT Descriptor 1 Incision and drainage of abscess (eg, carbuncle, suppurative hidradenitis, cutaneous or subcutaneous abscess, cyst, furuncle, or paronychia); simple or single

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
57452	000	1.50	**RUC Time**	10,566

CPT Descriptor 2 Colposcopy of the cervix including upper/adjacent vagina;

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 14 **% of respondents:** 31.8 **%**

TIME ESTIMATES (Median)	**CPT Code: 11980**	**Key Reference CPT Code:** 55876	**Source of Time** **RUC Time**

Median Pre-Service Time	10.00	29.00
Median Intra-Service Time	12.00	20.00
Median Immediate Post-service Time	5.00	10.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**27.00**	**59.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.29	2.86
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.21	3.07
Urgency of medical decision making	2.14	2.64
Technical Skill/Physical Effort (Mean)		
Technical skill required	3.07	3.36
Physical effort required	2.71	2.79
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	2.71	3.21
Outcome depends on the skill and judgment of physician	3.00	3.21
Estimated risk of malpractice suit with poor outcome	2.57	2.93

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	2.57	2.79
Intra-Service intensity/complexity	3.00	3.14
Post-Service intensity/complexity	2.36	2.29

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The AUA sent a "do you do letter" to a random number of members. The surveys were then sent to the individual physicians who answered that they do the procedure and would complete the RUC survey. The survey was sent to 87 individuals and of those individuals, 49 responses were received for a response rate of 56.32%. In 2013, 22,910 of these procedures were performed in the Medicare population so the number of responses to this survey meets the new RUC criteria of 30 respondents as the minimum survey sample size for this code.

The AUA RUC expert panel reviewed the survey results. The expert panel added two minutes of positioning time in the pre-service time. The current intraservice time is 12.5 minutes. The survey results for intraservice time came to 12 minutes. The current work RVU is 1.48. The median work value from the survey is 2.10. The 25th percentile of the work RVU was 1.69. The survey median postservice time was five minutes and the expert panel suggests that time be considered instead of the postservice time package for this procedure.

Since there was a minimal reduction in the intraservice time, it is the recommendation of the AUA RUC expert panel that the current RVU of 1.48 be maintained for CPT code 11980.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 11980

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Urology How often? Commonly

Specialty Radiation Oncology How often? Sometimes

Specialty Diagnostic Radiology How often? Rarely

Estimate the number of times this service might be provided nationally in a one-year period? 21531
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. Medicare X 125%

Specialty Urology Frequency 16421 Percentage 76.26 %

Specialty Radiation Oncology Frequency 3938 Percentage 18.28 %

Specialty Diagnostic Radiology Frequency 776 Percentage 3.60 %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 17,225 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. RUC Database

Specialty Urology Frequency 13137 Percentage 76.26 %

Specialty Radiation Oncology Frequency 3150 Percentage 18.28 %

Specialty Diagnostic Radiology Frequency 620 Percentage 3.59 %

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Skin

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 11980

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

SS Rec Summary

ISSUE: 11980 Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)

TAB: 20

Source	CPT	DESC	Resp	IWPUT	RVW MIN	RVW 25th	RVW MED	RVW 75th	RVW MAX	Total Time	PRE-TIME EVAL	PRE-TIME POSIT	PRE-TIME SDW	INTRA-TIME MIN	INTRA-TIME 25th	INTRA-TIME MED	INTRA-TIME 75th	INTRA-TIME MAX	IMMD POST
REF	55876	Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple		0.0428			1.73			59.00	19.00	10.00				20.00			10.00
CURRENT	11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)		0.0826			1.48			32.50	15.00					12.50			5.00
SVY	11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)	44		1.19	1.69	2.10	2.60	4.50	38.00	13.50	3.00	5.00	5.00	10.00	12.00	15.00	20.00	5.00
REC	11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)			1.10						7.00	2.00	1.00			12.00			5.00

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:

11980

Global Period: xxx Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee: RUC Advisors from each specialty society involved in this survey process reviewed the practice expense recommendations and approved them.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: We are using existing CPT code inputs as reference code.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Visit prior to procedure:
Provide pre-service education and obtain consent from patient

Day of Procedure – Pre-Service
Greet the patient
Provide gown
Ensure appropriate medical records are available
Obtain three vitals (BP, weight and temperature)
Prepare room, equipment and supplies

Intra-Service Clinical Labor Activities:

Assist physician during procedure

Post-Service Clinical Labor Activities:

Clean the room and equipment
Provide follow up information to patient.
Patient education/teaching as appropriate based upon the visit
Confers with the MD verbally for any last minute instructions for patient.
Next appointment is set up for patient while checking out.

Next day after patient leaves the office, calls patient.

	A	B	C	D	E	F	G
1				EXISTING INPUTS			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**CPT Code # 11980**		**CPT Code # 11980**	
3	**Meeting Date: January 2014 Tab: 20 Specialty: American Urological Association**	**CMS Code**	**Staff Type**	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)		Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)	
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**
6	**TOTAL CLINICAL LABOR TIME**	**L037D**	**RN/LPN/MTA**	**32.5**	**5.0**	**45.0**	**0.0**
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**15.0**	**5.0**	**0.0**	**0.0**
8	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**17.5**	**0.0**	**42.0**	**0.0**
9	**TOTAL POST-SERV CLINICAL LABOR TIME**			**0.0**	**0.0**	**3.0**	**0.0**
10	**PRE-SERVICE**						
11	**Start: Following visit when decision for surgery or procedure made**						
12	Complete pre-service diagnostic & referral forms						
13	Coordinate pre-surgery services						
14	Schedule space and equipment in facility				**5**		
15	Provide pre-service education/obtain consent			**15**			
16	Follow-up phone calls & prescriptions						
17	*Other Clinical Activity - *specify:*						
18	**End: When patient enters office/facility for surgery/procedure**						
19	**SERVICE PERIOD**						
20	**Start: When patient enters office/facility for surgery/procedure:**						
21	Greet patient, provide gowning, ensure appropriate medical records are available					**3**	
22	Obtain vital signs					**3**	
23	Provide pre-service education/obtain consent					**3**	
24	Prepare room, equipment, supplies					**2**	
25	Prepare and position patient/ monitor patient/ set up IV					**2**	
26	Sedate/apply anesthesia					**2**	
27	**Intra-service**						
28	Assist physician in performing procedure	**L037D**	**RN/LPN/MTA**	**12.5**		**12**	
29	Assist physician/moderate sedation (100% of physician time)						
30	**Post-Service**						
31	Monitor pt. following moderate sedation						
32	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)						
33	Clean room/equipment by physician staff			**5**		**3**	
34	Clean Surgical Instrument Package					**10**	
35	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions					**2**	
36	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)			**n/a**		**n/a**	
37	Dischrg mgmt (1.0 x 99238) (enter 12 min)			**n/a**		**n/a**	
38	Dischrg mgmt (1.0 x 99239) (enter 15 min)			**n/a**		**n/a**	
39	**End: Patient leaves office**						
40	**POST-SERVICE Period**						
41	**Start: Patient leaves office/facility**						
42	Conduct phone calls/call in prescriptions					**3**	
43	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**
44	99211 16 minutes		16				
45	99212 27 minutes		27				
46	99213 36 minutes		36				
47	99214 53 minutes		53				
48	99215 63 minutes		63				
49	**Total Office Visit Time**			**0.0**	**0.0**	**0.0**	**0.0**
50	*Other Clinical Activity - *specify:*						
51	**End: with last office visit before end of global period**						
52	**MEDICAL SUPPLIES****	**CODE**	**UNIT**				
53	pack, minimum multi-specialty visit	SA048	pack	**1**		**1**	
54	drape, non-sterile, sheet 40 in x 60 in	SB006	item	**1**			
55	gloves, sterile	SB024	item	**1**		**2**	
56	gauze, sterile, 4in x 4in	SG055	item	**2**		**2**	
57	tape, surgical paper 1 in (micropore)	SB079	item	**12**		**12**	
58	syringe-needle, OSHA compliant	SC058	item			**1**	
59	drape, sterile, for Mayo stand	SB012	item			**1**	
60	drape, sterile, three-quarter sheet	SB014	item			**1**	
61	Underpad, 2 ft x 3 ft (Chux)	SB044	item			**1**	
62	blade, surgical, super-sharp	SF044	item			**1**	
63	providone swabstick	SJ043	item			**1**	
64	steri-strip	SG074	item			**1**	
65	lidocaine 1%-2% inj (Xylocaine)	SH047	ml	**1**		**10**	
66	**EQUIPMENT**	**CODE**					
67	instrument pack, basic ($500)	EQ137		**13**		**24**	
68	table, power	EF031		**40**		**32**	
69	table, instrument, mobile	EF027				**22**	
70	light, exam	EQ168				**22**	
71							

AMA/Specialty Society RVS Update Committee Summary of Recommendations
High Volume Growth screen

January 2014

Injection for Knee Arthrography

At the October 2013 meeting, the Relativity Assessment Workgroup reviewed High Volume Growth Services where Medicare utilization increased by at least 100% from 2006 to 2011. The RUC requested that these services be surveyed for physician work and develop practice expense inputs. At the February 2014 CPT Editorial Panel meeting, the specialty societies submitted a Code Change Proposal (CCP) to address the high growth of this code. The Panel approved editorial revisions replacing the term "procedure" for "of contrast." This revision to the descriptor clarifies that the correct use of 27370 is to describe the injection of contrast into the knee joint space for arthrography only. The specialty societies noted that the high volume growth for this procedure is likely due to its being reported incorrectly as arthrocentesis or aspiration. The correct reporting of those services is CPT code 20610 *Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance* (work RVU= 0.79).

Work Neutrality:
The RUC's recommendation for these codes will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

CPT Code (•New)	Tracking Number	CPT Descriptor	Global Period	Work RVU Recommendation
Introduction or Removal				
▲20610		Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, ~~joint~~ subacromial bursa); without ultrasound guidance		
●*2060X3*		*with ultrasound guidance, with permanent recording and reporting*		
		(If fluoroscopic, CT or MRI guidance is performed, see 77002, 77012, or 77021)		
		(Do not report 20610, 2060X3 in conjunction with 27370, 76942)		

27370		Injection ~~procedure~~ of contrast for knee arthrography *(For radiological supervision and interpretation, use 73580. Do not report 77002 in conjunction with 73580)* (Do not report 27370 in conjunction with 20610, 2060X3, 29871) (For arthrocentesis of the knee or injection other than contrast, use 20610, 2060X3) (For arthroscopic lavage and drainage of the knee, use 29871)	000	Editorial Revisions made by CPT Editorial Panel
Endoscopy/Arthroscopy *29871* *Arthroscopy, knee, surgical; for infection, lavage and drainage* *(For implantation of osteochondral graft for treatment of articular surface defect, see 27412, 27415, 29866, 29867)* (Do not report 29871 in conjunction with 27370)				

ACR
AMERICAN COLLEGE OF RADIOLOGY
QUALITY IS OUR IMAGE

January 7, 2014

Barbara Levy, MD
Chair, AMA/Specialty Society RVS Update Committee
American Medical Association
515 North State Street
Chicago, Illinois 60654

Subject: Injection for Knee Arthrography

Dear Dr. Levy,

CPT code 27370 *(Injection procedure for knee arthrography)* was identified by the RAW through the High Volume Growth screen and requested by the RUC to survey for the January 2014 RUC meeting. This code is being addressed through the CPT Editorial Panel with a CCP to be discussed at the February 2014 CPT meeting. Therefore, we did not survey 27370 for the January 2014 RUC.

Should you have any questions, please feel free to contact ACR RUC staff, Stephanie Le, at 800-227-5463, ext. 4584 or via email sle@acr.org.

Sincerely,

Ezequiel Silva, III, MD
ACR RUC Advisor

William Creevy, MD
AAOS RUC Advisor

cc: Sherry Smith
Rosa Karbowiak

AMA/Specialty Society RVS Update Committee Summary of Recommendations
High Volume Growth screen

January 2014

Endobronchial Ultrasound (EBUS)

In October 2013, the Relativity Assessment Workgroup reviewed High Volume Growth Services where Medicare utilization increased by at least 100% from 2006 to 2011. The RUC requested that these services be surveyed for physician work and develop practice expense inputs.

The specialty societies indicated and the RUC agreed that there has been a change in instrumentation and typical patient due to new technology. The equipment for Endobronchial Ultrasound (EBUS) has evolved since CPT code 31620 was last surveyed and evaluated by the RUC in 2004. The physician work has changed in the following ways:

1) Currently there is a separate bronchoscope that has the EBUS probe built into the tip. This is the standard technique for obtaining EBUS guided biopsies from mediastinal and hilar locations.
2) The technique for using the newer bronchoscope requires the acquisition of new skills as the camera is at a 30 degree angle from the tip of the scope. The operator has to navigate the bronchoscope looking at the airway from an angle rather than the end of the scope.
3) The ultrasound is visualized in real time during the biopsy procedure, and needs to be continuously adjusted in the field of view. This is a change from the prior technique in which the target was visualized and then the ultrasound (US) catheter removed to allow for the biopsy needle/forceps to be inserted into the same channel.

The RUC reviewed the survey responses from 256 physicians and determined that the survey 25th percentile work RVU of 1.50 and survey 25th percentile physician intra-service time of 40 minutes appropriately accounts for the physician work and time required to perform this service. The RUC questioned whether this add-on code could be used as an add-on to a variety of different codes that already include the work of performing a biopsy. The specialty societies clarified that the work of base code 31629 *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)* (work RVU = 4.09 and 30 minutes intra-service time) includes the insertion of the standard bronchoscope, surveying the airways, and removal of the bronchoscope. Following this, CPT code 31620 is reported when the EBUS scope is inserted and the physician surveys all the lymph nodes. The intra-service work of CPT code 31620 ends when the biopsies begin. EBUS is merely the vehicle to get to the biopsies and does not include the work of performing the biopsies. The biopsy work is included in the base code 31629. For example, the intra-service work for 31629 is 30 minutes, 25 minutes of that time is to insert the bronchoscope and 5 minutes to perform the biopsy, in the middle of those two functions are 40 minutes to insert the EBUS and preparing to perform the biopsy.

The RUC questioned whether or not the survey respondents excluded the physician work and time to perform the biopsy when they estimated their times. To ensure that the valuation of this service does not include duplicative physician work with conducting the biopsy, the RUC determined that the survey 25th percentile intra-service time of 40 minutes is more appropriate. The RUC compared 31620 to key reference service *31633 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), each additional lobe* (work RVU = 1.32 and 20 minutes of intra-service time) and determined that the key reference service is less intense and complex and requires half the physician time to perform and therefore is valued lower. For additional support, the RUC referenced similar add-on code 13122 *Repair, complex, scalp, arms, and/or legs; each additional 5 cm or less (List separately in addition to code for primary procedure)* (work RVU = 1.44 and 30 minutes intra-service) which requires slightly less physician work and time to perform. **The RUC recommends a work RVU of 1.50 for CPT code 31620**.

Refer to CPT
The RUC recommends referring CPT code 31620 to the CPT Editorial Panel to clarify that there is no overlap regarding the work of performing the biopsy(ies) associated with base code 31629 and other base codes in which add-on CPT code 31620 would be typically be reported.

Flag in RUC Database
Due to the use of the 25th percentile physician time, the RUC recommends flagging CPT code 31620 in the RUC database as not to use to validate for physician work or time.

Practice Expense
The RUC recommends the direct practice expense inputs as presented and accepted by the Practice Expense Subcommittee.

CPT Code (•New)	CPT Descriptor	Global Period	Work RVU Recommendation
31620	Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s]) (Use 31620 in conjunction with 31622-31646)	ZZZ	1.50

CHEST Commentary

The Changing Face of Outpatient Bronchoscopy in 2013

Scott Manaker, MD, PhD, FCCP; and Anil Vachani, MD, MSCE

In 2013, the outpatient hospital payment from Medicare for a transbronchial needle aspiration more than doubled. At the same time, the recently updated American College of Chest Physicians guidelines for the diagnosis and management of lung cancer now recommend needle techniques, such as transbronchial needle aspiration, over surgical staging. The convergence of these two events will accelerate the existing forces of technology and economics that have been influencing both the practices of outpatient bronchoscopy and mediastinoscopy and the management of patients with lung cancer over the past 20 years. ***CHEST 2013; 143(5):1214–1218***

Abbreviations: APC = Ambulatory Payment Classification; CPT = Current Procedural Terminology; EBUS = endobronchial ultrasound; NCD = national coverage determination; TBNA = transbronchial needle aspiration

On January 1, 2013, the outpatient hospital payment from Medicare for transbronchial needle aspiration (TBNA) more than doubled, rising by > $800 over the 2012 reimbursement (Table 1).[1-3] TBNA (along with bronchoscopy for balloon occlusion) has moved from the lower reimbursing Ambulatory Payment Classification (APC) 0074 for diagnostic bronchoscopy to the higher reimbursing APC code 0415 for therapeutic bronchoscopy (Table 1). This move of TBNA to APC 0415 is coupled with a 23% decrease in payments from Medicare for APC 0415 as part of the annual rebasing of the hospital outpatient prospective payment system to achieve budget neutrality.[2] This annual adjustment consequently lowers the reimbursement of all other therapeutic bronchoscopic procedures while increasing payments for TBNA. Parallel changes in outpatient hospital bronchoscopy payment will likely occur from other payers to the extent that facility contracts with private insurers reflect changes in Medicare payment rates.

Such large changes in reimbursement raise several possibilities about the future use of endobronchial ultrasound (EBUS), TBNA, and other therapeutic bronchoscopy procedures in APC 0415. The increase in reimbursement for TBNA may motivate additional outpatient facilities to provide TBNA, further disseminating this technology and leading to an appropriate increase in the use of TBNA for the evaluation of thoracic disease. Alternatively, this increase could produce adverse consequences, such as an acceleration of inappropriate TBNA procedures and associated contribution to the rising costs of health care.[4] Regardless of the propriety, increases in TBNA will likely accentuate the reduction in mediastinoscopies observed over the past 5 years (Fig 1).[5]

The primary role of TBNA has evolved, and now plays a central role in the evaluation of patients with potential malignancy.[6-8] This evolution occurred upon a backdrop of extraordinary change in the clinical care of such patients over the past 20 years. Before 1990, patients with an abnormality on their chest radiograph were followed with serial routine radiographs, often supplemented with CT scans or surgical lung biopsy specimen or mediastinoscopy evaluation. Worrisome growth of abnormalities demonstrated radiographically typically prompted proceeding with surgical biopsy. For the next 2 decades, advances in chest CT imaging, TBNA, transthoracic needle aspiration, video-assisted thoracic surgery, PET scanning, bronchoscopic imaging

Manuscript received January 9, 2013; revision accepted January 12, 2013.
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Correspondence to: Scott Manaker, MD, PhD, FCCP, Department of Medicine, Pulmonary, Allergy, and Critical Care Division, Perelman School of Medicine at the University of Pennsylvania, 8 Penn Tower, Ste 800, One Convention Ave, Philadelphia, PA 19104-4283; e-mail: scott.manaker@uphs.upenn.edu

DOI: 10.1378/chest.13-0066

Table 1—*CPT Codes Assigned to Bronchoscopy APCs for 2012 to 2013 With Corresponding Base Payment Rates*

Bronchoscopy APC	2012	2013
APC 0074 level 1 lower airway endoscopy	$733.21	$763.92
	31622, diagnostic bronchoscopy	31622, diagnostic bronchoscopy
	31623, bronchoscopy with brushings	31623, bronchoscopy with brushings
	31624, bronchoscopy with BAL	31624, bronchoscopy with BAL
	31645, initial therapeutic aspiration bronchoscopy	31645, initial therapeutic aspiration bronchoscopy
	31646, subsequent aspiration bronchoscopy	31646, subsequent aspiration bronchoscopy
	31625, bronchoscopy with endobronchial biopsy	31625, bronchoscopy with endobronchial biopsy
	31628, bronchoscopy with transbronchial biopsy	31628, bronchoscopy with transbronchial biopsy
	31632, transbronchial biopsy in an additional lobe	31632, transbronchial biopsy in an additional lobe
	31629, transbronchial needle aspiration	
	31633, transbronchial needle aspiration in an additional lobe	
	31634, balloon occlusion bronchoscopy	
	31635, foreign body removal bronchoscopy	31635, foreign body removal bronchoscopy
	31643, brachytherapy bronchoscopy	31643, brachytherapy bronchoscopy
	31656, bronchoscopic bronchography	
APC 0415 level 2 lower airway endoscopy	$2,023.82	$1,561.61
	0250T, bronchial valve insertion	31647, bronchial valve insertion
		31651, bronchial valve insertion, each additional lobe
	0251T, bronchial valve removal	31648, bronchial valve removal
		31649, bronchial valve removal, each additional lobe
	0276T, bronchial thermoplasty, one lobe	31660, bronchial thermoplasty, one lobe
	0277T, bronchial thermoplasty, two or more lobes	31661, bronchial thermoplasty, two or more lobes
	31640, bronchoscopic tumor excision, any method	31640, bronchoscopic tumor excision, any method
	31641, laser bronchoscopy	31641, laser bronchoscopy
	31630, bronchoscopy with balloon dilation	31630, bronchoscopy with balloon dilation
	31626, bronchoscopy with fiducial marker placement	31626, bronchoscopy with fiducial marker placement
		31629, transbronchial needle aspiration
		31633, transbronchial needle aspiration in an additional lobe
		31634, balloon occlusion bronchoscopy
	31631, tracheal stent placement	31631, tracheal stent placement
	31638, any (tracheal or bronchial) stent revision	31638, any (tracheal or bronchial) stent revision
	31636, bronchial stent placement	31636, bronchial stent placement

Note the significant change in facility payments associated with the shift of transbronchial needle aspirations and balloon occlusion bronchoscopies from APC 0074 to APC 0415 in 2013. In 2013, CPT 31656 for bronchoscopic bronchography was deleted and should be reported with the unlisted code 31899. Also in 2013, CPT created 31647 to 31649 and 31651 to replace 0250T and 251T; and created 31660 and 31661 to replace 0276T and 0277T, respectively. APC = Ambulatory Payment Classification; CPT = Current Procedural Terminology.

with EBUS, endoscopic ultrasound with fine needle aspiration of mediastinal lymph nodes, and navigational bronchoscopy all led to iterative changes in the diagnosis and staging of thoracic malignancies. Since 2011, the potential for low-dose chest CT scan screening to evaluate patients at high risk for lung cancer may lead to increased use of many of these diagnostic modalities.[9]

The initial dissemination and integration into clinical practice of many of these technologies has been delayed both by the time necessary to develop appropriate Current Procedural Terminology (CPT) codes to report these services to payers[5,10-12] and by adverse coverage determinations. For example, although PET scanning was developed in the early 1990s, the first national coverage determination (NCD) by Medicare did not occur until 1999, effective retrospectively to January 1, 1998, and limited PET scanning to the evaluation of solitary pulmonary nodules and the initial staging of non-small cell lung cancer.[13] Expansion of the NCD to restaging in patients with non-small cell lung cancer lagged until 2001.[13] Some payers did not cover EBUS until 2011,[14] and many still fail to cover navigational bronchoscopy because it is considered experimental, investigational, or unproven.[15] Despite support from a multispecialty society coalition advocating the integration of low-dose CT screening into clinical practice,[16] neither an NCD from Medicare nor a ruling from the US Preventive Services Task Force has been issued.

With the delays in integrating technological advances into routine clinical practice conferred by the reimbursement and coverage processes, the increase in EBUS use did not begin until 2005, when coverage for EBUS was initiated[5] (Fig 1). For the initial 3 years

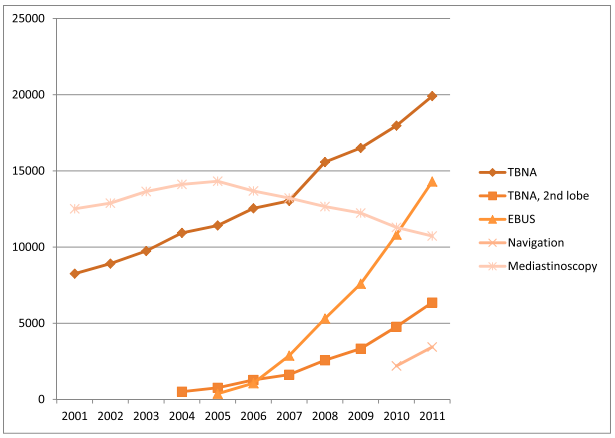

FIGURE 1. Medicare-paid claims by calendar year. For EBUS, navigation bronchoscopy, and TBNA, paid Medicare claims data begin in the calendar year following development and publication of a Current Procedural Terminology (CPT) code. CPT codes for each procedure are as follows: TBNA, 31629; TBNA, second lobe, 31633; EBUS, 31620; navigational bronchoscopy, 31627; and mediastinoscopy, 39400. EBUS = endobronchial ultrasound; TBNA = transbronchial needle aspiration.

after the 2005 implementation of CPT code 31620 for EBUS,[10] Medicare allowed a transitional pass-through payment to an outpatient hospital facility for each bronchoscopy that included performance of EBUS.[17] The initial payments of $1,731 in 2005 rose to $1,985 by 2007.[18,19] Following expiration of this transitional pass-through payment and packaging of EBUS as intrinsic to the underlying base bronchoscopy in 2008,[20] no separate payment occurred for EBUS; rather, an additional $49 was added to each of the diagnostic bronchoscopies in APC 0074, regardless of whether EBUS was performed. Such payment policy increased reimbursement for all diagnostic bronchoscopies in APC 0074 and obliterated any financial incentive for excessive or inappropriate use of EBUS; the bronchoscopist could use EBUS during bronchoscopy as clinically appropriate.

Even after expiration of the transitional pass-through payment, EBUS use continued to increase rapidly between 2008 and 2011[5] (Fig 1). Clearly, prior fears that falling facility reimbursement would reduce EBUS have not come to pass.[5,19] Coupled with this persistent, steep increase in the number of bronchoscopies performed that incorporate EBUS (and TBNA), there has been a slow, but steady fall in the number of mediastinoscopies (Fig 1). The most current Medicare data from 2011 revealed that the use of mediastinoscopy has fallen by > 25% from the peak in 2005, and these data pose many unanswered questions.[5]

Whether the reduction in mediastinoscopy noted in the Medicare population is attributable solely to cases diagnosed or staged from a bronchoscopic procedure remains unknown. Although mediastinoscopy has traditionally been considered as the gold standard staging procedure in clinically appropriate cases,[21] several studies suggested that imaging-guided bronchoscopic biopsy confers an equivalent diagnostic yield with fewer complications in patients with malignancy[7,22-25] and may lead to a lower rate of noncurative resection. The increasing importance of histologic subclassification and acquisition of sufficient diagnostic material to allow for molecular testing will further fuel this controversy. Although most easily accomplished through a surgical approach, recent evidence suggests that these important modern diagnostic tasks are successfully performed in the majority of cases that use cytologic material obtained with bronchoscopy.[26] It is also unclear whether parallel reductions in mediastinoscopy performance rates will occur in non-Medicare populations, especially in light of delayed coverage by other payers for imaging-guided bronchoscopy.[14,15] Arguably, the most important question may be the comparative cost-effectiveness of mediastinoscopy vs imaging-guided bronchoscopy in diagnosing and staging intrathoracic malignancy.[27,28]

Converse to the experience with EBUS, the 2013 changes in facility reimbursement could affect the use of a large number of diagnostic and therapeutic bronchoscopic procedures. The new facility reimbursement rates are not anticipated to lead to changes in the total expenditures for bronchoscopy because the expected volumes of each bronchoscopic procedure are calculated into the payment rate for each APC; that is, the fall in reimbursement for each procedure assigned to APC 0415 will be offset by the increase in the volumes of that APC occurring from the movement of TBNA to APC 0415.[2] Likewise, the small increase in the outpatient hospital payment for APC 0074 should accommodate the fall in volume of APC 0074 by the departure of TBNA.[2]

The 23% fall in reimbursement for APC 0415 for calendar year 2013 (Table 1) might engender fear that patient access to medically necessary, advanced therapeutic bronchoscopic services will be severely curtailed. Such fears would echo the outcry within the pulmonary community in 2008, when the transitional pass-through payment for EBUS expired.[19] Fortunately, the steady growth of EBUS (and TBNA) over the past several years,[5] despite the fall in reimbursement in 2008, portends no adverse impact on the use of lasers, stents, and other advanced therapeutic bronchoscopies in APC 0415 that resulted from the decrease in facility reimbursement for these procedures. Furthermore, the reimbursement (both technical revenues, such as APC payments, to facilities and professional fees to physicians) for the families of both diagnostic bronchoscopies in APC 0074 and advanced therapeutic bronchoscopies in APC 0415 represents a small fraction of the overall revenues generated in the care of patients with thoracic

malignancies.[5] The economic incentives for a robust interventional pulmonology program lie within the downstream revenues accruing to a facility for the disease-state care of these patient populations.[29,30]

An additional consideration of the 2013 reimbursement change centers on whether the increasing rate of EBUS performance will remain constant, or further accelerate.[5] Because TBNA is increasingly performed with EBUS guidance, any incentives for increased TBNA use, whether clinical or economic, will also drive further use of EBUS. Independent technological drivers of EBUS use, such as the performance of peripheral EBUS with navigational bronchoscopy or during fiducial placement, will also affect future EBUS volume. Certainly, the addition of CPT code 31627 for navigational bronchoscopy[11] will stimulate EBUS performance in elderly patients because Medicare currently covers this service (Fig 1).[5] However, payment policies from numerous other payers that currently withhold reimbursement for navigational bronchoscopy may sharply curtail this impact in other patient populations.[15,31-34]

The most uncertainty regarding the 2013 outpatient hospital reimbursement schedule centers on the impact on TBNA performance volumes. Novel forms of reimbursement, including bundled payments, shared savings, and accountable care organizations[35,36] designed to improve quality and reduce total health-care expenditures, will facilitate the potential allocation of windfall reimbursement accruing from TBNA at facilities to physicians. Certainly, these economic considerations risk inappropriate performance of TBNA akin to data suggesting the inappropriate performance of cardiac catheterizations and cardiac stress testing as a consequence of financial incentives to perform these procedures.[37,38] In fact, the seemingly inappropriate use of cardiac stress testing is greater when performed by physicians who billed for both the professional and the technical fees as a consequence of office-based procedures.[39] In parallel to the change in facility-based reimbursement for TBNA, the recent update of the American College of Chest Physician guidelines on lung cancer staging recommends the use of needle techniques (EBUS-TBNA, endoscopic ultrasound with fine needle aspiration, or both) over surgical staging as the best first test.[40]

Both the increased reimbursement for TBNA and the new guideline recommendations will lead to continued growth of needle techniques for the diagnosis and management of known or suspected lung cancer and potential further reductions in mediastinoscopy. It behooves endoscopists to adequately document the medical indications for TBNA in anticipation of the almost certain prepayment and postpayment reviews of these now highly reimbursed and frequently performed procedures.[41,42] We expect the pulmonary community to continue as responsible stewards of our limited health-care resources but in accord with the new guidelines applicable to their patients[40] and not driven by windfall profits to the facilities where they practice.[29,30]

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CHEST Supplement

DIAGNOSIS AND MANAGEMENT OF LUNG CANCER, 3RD ED: ACCP GUIDELINES

Methods for Staging Non-small Cell Lung Cancer

Diagnosis and Management of Lung Cancer, 3rd ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines

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Background: **Correctly staging lung cancer is important because the treatment options and prognosis differ significantly by stage. Several noninvasive imaging studies and invasive tests are available. Understanding the accuracy, advantages, and disadvantages of the available methods for staging non-small cell lung cancer is critical to decision-making.**

Methods: **Test accuracies for the available staging studies were updated from the second iteration of the American College of Chest Physicians Lung Cancer Guidelines. Systematic searches of the MEDLINE database were performed up to June 2012 with the inclusion of selected meta-analyses, practice guidelines, and reviews. Study designs and results are summarized in evidence tables.**

Results: **The sensitivity and specificity of CT scanning for identifying mediastinal lymph node metastasis were approximately 55% and 81%, respectively, confirming that CT scanning has limited ability either to rule in or exclude mediastinal metastasis. For PET scanning, estimates of sensitivity and specificity for identifying mediastinal metastasis were approximately 77% and 86%, respectively. These findings demonstrate that PET scanning is more accurate than CT scanning, but tissue biopsy is still required to confirm PET scan findings. The needle techniques endobronchial ultrasound-needle aspiration, endoscopic ultrasound-needle aspiration, and combined endobronchial ultrasound/endoscopic ultrasound-needle aspiration have sensitivities of approximately 89%, 89%, and 91%, respectively. In direct comparison with surgical staging, needle techniques have emerged as the best first diagnostic tools to obtain tissue. Based on randomized controlled trials, PET or PET-CT scanning is recommended for staging and to detect unsuspected metastatic disease and avoid noncurative resections.**

Conclusions: **Since the last iteration of the staging guidelines, PET scanning has assumed a more prominent role both in its use prior to surgery and when evaluating for metastatic disease. Minimally invasive needle techniques to stage the mediastinum have become increasingly accepted and are the tests of first choice to confirm mediastinal disease in accessible lymph node stations. If negative, these needle techniques should be followed by surgical biopsy. All abnormal scans should be confirmed by tissue biopsy (by whatever method is available) to ensure accurate staging. Evidence suggests that more complete staging improves patient outcomes.**

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Abbreviations: APW = aortopulmonary window; EBUS = endobronchial ultrasound; EUS = endoscopic ultrasound; FDG = F-fluoro-2-deoxy-D-glucose; FN = false-negative; FP = false-positive; LUL = left upper lobe; NA = needle aspiration; NPV = negative predictive value; NSCLC = non-small cell lung cancer; PPV = positive predictive value; RCT = randomized controlled trial; SCLC = small cell lung cancer; TBNA = transbronchial needle aspiration; TN = true-negative; TP = true-positive; TTNA = transthoracic needle aspiration; VATS = video-assisted thoracic surgery

Summary of Recommendations

General Approach

2.1.1. For patients with either a known or suspected lung cancer who are eligible for treatment, a CT scan of the chest with contrast is recommended (Grade 1B)**.**

Remark: If PET scan is unavailable for staging, the CT of the chest should be extended to include the liver and adrenal glands to assess for metastatic disease.

2.1.2. For patients with either a known or suspected lung cancer, it is recommended that a thorough clinical evaluation be performed to provide an initial definition of tumor stage (Grade 1B)**.**

2.1.3. In patients with either a known or suspected lung cancer who have an abnormal clinical evaluation and no suspicious extrathoracic abnormalities on chest CT, additional imaging for metastases is recommended (Grade 1B)**.**

Remark: Site specific symptoms warrant directed evaluation of that site with the most appropriate study.

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Extrathoracic Staging

3.1.1. In patients with a normal clinical evaluation and no suspicious extrathoracic abnormalities on chest CT being considered for curative-intent treatment, PET imaging (where available) is recommended to evaluate for metastases (except the brain) (Grade 1B)**.**

Remark: Ground glass opacities and an otherwise normal chest CT do not require a PET scan for staging.

Remark: In patients with peripheral stage cIA tumors a PET scan is not required.

Remark: If PET is unavailable, bone scan and abdominal CT are reasonable alternatives to evaluate for extrathoracic disease.

3.1.2. In patients with an imaging finding (eg, by PET) suggestive of a metastasis, further evaluation of the abnormality with tissue sampling to pathologically confirm the clinical stage is recommended prior to choosing treatment (Grade 1B)**.**

Remark: Tissue sampling of the abnormal site is imperative so that the patient is not excluded from potentially curative treatment.

Remark: Tissue sampling of a distant metastatic site is not necessary if there is overwhelming radiographic evidence of metastatic disease in multiple sites.

Remark: Tissue sampling of the mediastinal lymph nodes does not necessarily need to be performed if there is overwhelming radiographic evidence of metastatic disease in multiple distant sites.

3.4.1. In patients with clinical stage III or IV non-small cell lung cancer (NSCLC) **it is suggested that routine imaging of the brain with head MRI (or CT if MRI is not available) should be performed, even if they have a negative clinical evaluation** (Grade 2C)**.**

Mediastinal Staging

4.4.2.1. For patients with extensive mediastinal infiltration of tumor and no distant metastases, it is suggested that radiographic (CT) assessment of the mediastinal stage is usually sufficient without invasive confirmation (Grade 2C)**.**

4.4.4.1. In patients with discrete mediastinal lymph node enlargement (and no distant metastases) with or without PET uptake in mediastinal nodes, invasive staging of the mediastinum

is recommended over staging by imaging alone (Grade 1C)**.**

4.4.4.2. In patients with PET activity in a mediastinal lymph node and normal appearing nodes by CT (and no distant metastases), invasive staging of the mediastinum is recommended over staging by imaging alone (Grade 1C)**.**

4.4.4.3. In patients with high suspicion of N2,3 involvement, either by discrete mediastinal lymph node enlargement or PET uptake (and no distant metastases), a needle technique (endobronchial ultrasound [EBUS]-needle aspiration [NA], EUS-NA or combined EBUS/EUS-NA) is recommended over surgical staging as a best first test (Grade 1B)**.**

Remark: This recommendation is based on the availability of these technologies (EBUS-NA, EUS-NA or combined EBUS/EUS-NA) and the appropriate experience and skill of the operator.

Remark: In cases where the clinical suspicion of mediastinal node involvement remains high after a negative result using a needle technique, surgical staging (eg, mediastinoscopy, video-assisted thoracic surgery [VATS], etc) should be performed.

Remark: The reliability of mediastinal staging may be more dependent on the thoroughness with which the procedure is performed than by which test is used.

4.4.6.1. In patients with an intermediate suspicion of N2,3 involvement, ie, a radiographically normal mediastinum (by CT and PET) and a central tumor or N1 lymph node enlargement (and no distant metastases), invasive staging of the mediastinum is recommended over staging by imaging alone (Grade 1C)**.**

4.4.6.2. In patients with an intermediate suspicion of N2,3 involvement, ie, a radiographically normal mediastinum (by CT and PET) and a central tumor or N1 lymph node enlargement (and no distant metastases), a needle technique (EBUS-NA, EUS-NA or combined EBUS/EUS-NA) is suggested over surgical staging as a best first test (Grade 2B)**.**

Remark: This recommendation is based on the availability of these technologies (EBUS-NA, EUS-NA or combined EBUS/EUS-NA) and the appropriate experience and skill of the operator.

Remark: In cases where the clinical suspicion of mediastinal node involvement remains high after a negative result using a needle technique, surgical staging (eg, mediastinoscopy, VATS, etc) should be performed.

Remark: The reliability of mediastinal staging may be more dependent on the thoroughness with which the procedure is performed than by which test is used.

4.4.8.1. For patients with a peripheral clinical stage IA tumor (negative nodal involvement by CT and PET), it is suggested that invasive preoperative evaluation of the mediastinal nodes is not required (Grade 2B)**.**

4.4.10.1. For the patients with a left upper lobe (LUL) cancer in whom invasive mediastinal staging is indicated as defined by the previous recommendations, it is suggested that invasive assessment of the Aortopulmonary Window (APW) nodes be performed (via Chamberlain, VATS, or extended cervical mediastinoscopy) if other mediastinal node stations are found to be uninvolved (Grade 2B)**.**

In patients in whom non-small cell lung cancer (NSCLC) has been demonstrated or is strongly suspected, consideration must turn toward determining the extent of the disease, or its stage, because this will impact directly on the management and prognosis. The first step is to identify whether the patient has distant metastatic disease or tumor confined to the chest, to determine whether treatment should be aimed at palliation or at potential cure. If disease is localized to the chest, the status of the mediastinal nodes becomes crucial in determining the best curative treatment strategy. Patients with stage IA, IB, IIA, and IIB disease can benefit from surgical resection; patients with stage IIIA, IIIB, and IV disease rarely meet the criteria for surgery.

Staging with regard to a patient's potential for surgical resection is most applicable to NSCLC. Except in rare cases of surgically operable limited-stage small cell lung cancer (SCLC), staging in the management of SCLC amounts to chemotherapy and radiation for limited disease or chemotherapy alone for extensive disease. Stage evaluation of patients with SCLC is similar but is not addressed in this article; it is covered by Jett et al[2] "Treatment of Small Cell Lung Cancer," in the American College of Chest Physicians (ACCP) Lung Cancer Guidelines.

This article addresses the identification of distant or extrathoracic metastatic disease in patients with lung cancer and examines imaging studies and invasive procedures that accurately determine the status of the mediastinum. The focus is on patients in whom there is a strong suspicion of lung cancer. Such a presumptive

clinical diagnosis is generally possible by an experienced physician after an assessment of risk factors and a review of the clinical presentation and the radiographic appearance on a CT scan. The next step is a clinical evaluation, consisting of a history and physical examination; the clinical evaluation and CT scan provide an initial presumptive definition of the clinical stage. In some cases, this is sufficiently reliable, but in most cases, the initial clinical stage must be confirmed with further tests. Many different tests are available, and selection of the right tests and their sequence has a major impact on how accurately and efficiently the patient's true clinical stage is determined. This iteration of the ACCP guidelines combines the articles that discussed noninvasive and invasive techniques in the previous iterations of the guidelines because it was recognized that from the clinical perspective, physicians use both methods together to accurately stage patients with lung cancer.[3,4]

When there is a strong suspicion of lung cancer, it is generally best to begin the process of stage evaluation before pursuing a diagnosis (see also Rivera et al,[5] "Establishing the Diagnosis of Lung Cancer," in the ACCP Lung Cancer Guidelines). In many situations, an invasive test can provide simultaneous confirmation of the diagnosis and its stage, leading to a more streamlined and efficient process. This requires a good understanding of which imaging findings need tissue confirmation and this is greatly aided by a multidisciplinary discussion of a patient's particular situation.

It seems intuitive that accurate staging of lung cancer is of paramount importance given the markedly different treatment options and prognosis for any given stage. Despite this, data have shown that the staging evaluation has often been carried out very poorly.[6-8] The impact of more thorough staging is marked. Farjah et al[6] assessed the use of multimodality staging for lung cancer among Medicare beneficiaries. They assessed the use of single (CT scan), bimodality (CT scan plus PET scan or CT scan plus invasive staging), or trimodality (CT, PET, and invasive staging) staging tests to assess for mediastinal metastases. At the end of the study period, only 30% had bimodality staging and 5% had trimodality staging, although the guidelines for many years have called for bimodality or trimodality staging in the majority of patients. After adjusting for differences in patient characteristics, those who underwent bimodality and trimodality staging had a significantly lower risk of death (hazard ratio, 0.58; 99% CI, 0.56-0.60; tri- vs single-modality: hazard ratio, 0.49; 99% CI, 0.45-0.54). These associations were maintained even after excluding various groups of poor-risk patients (eg, stage IV, anyone suffering early death within 1 month, patients not treated within 6 months, and so forth). These results may reflect unidentified sources of residual confounding, and it is likely that better staging serves as a marker for better care in general. Nevertheless, there can be little doubt that basing treatment decisions on poorly executed staging evaluations may well lead to suboptimal treatment and worse outcomes.

1.0 Methods

The authors updated a systematic review of the diagnostic accuracy of different staging methods for patients with NSCLC. A more complete description of the methods can be found in the first edition of the ACCP guidelines.[3,4,9,10] Briefly, computerized searches of MEDLINE covering January 1991 to May 2006 for the previous guidelines and January 2006 to June 2012 for this iteration were performed. In addition, we searched the reference lists of included studies, practice guidelines, systematic reviews, and meta-analyses to ensure that all relevant studies were identified. Only articles published in English were considered. The search strategy and results are available on request. The searches were structured around the following population, intervention, comparator, outcomes (PICO) questions (detailed in Table 1S):

1. What is the role of PET scan in the staging of patients with NSCLC?
2. What is the impact of mediastinal staging by imaging and invasive staging procedures in patients with NSCLC?

1.1 Selection Criteria

Titles and abstracts, and the full text of all articles passing the title-and-abstract screen, were evaluated independently by three of the authors (G. S., A. G., M. J.) for inclusion or exclusion based on the following five criteria: (1) publication in a peer-reviewed journal; (2) a study size of $\geq$ 20 patients (except for studies involving CT scan evaluation of the mediastinum or mediastinoscopy, which required a study size of $\geq$50 patients); (3) patient group not included in a subsequent update of the study; (4) for noninvasive staging methods, histologic or cytologic confirmation of mediastinal nodes or extrathoracic sites in addition to the primary tumor; for invasive staging methods, confirmation of mediastinal nodal biopsy results by histology at the time of resection, or long-term clinical follow-up ($\geq$1 year); and (5) availability of the raw data needed to calculate independently the sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV), or the raw data needed to calculate the NPV of the clinical evaluation. Disagreements were resolved by consensus.

The data abstraction was performed for patients suspected of having lung cancer (eg, NSCLC, SCLC). Where possible, patients suspected of a diagnosis other than lung cancer were excluded. A definite diagnosis of any lung cancer in the mediastinal tissues was considered positive, whereas other diagnoses (benign disease, lymphoma, and so forth) were coded as negative for lung cancer. Equivocal test results were considered negative. Data were abstracted and results were tabulated on a per-patient basis, not per lymph node station. Calculation of subtotal or total summary performance characteristics was accomplished by calculating a median of the values (sensitivity, specificity, and other values) from each study; in other words, no weighting according to study size was performed. This method was chosen because of its simplicity. In this iteration of the guidelines, randomized controlled trials (RCTs) comparing the use of noninvasive staging tests with

control and those making comparisons among invasive staging techniques are reported separately.

Various parameters, including sensitivity, specificity, PPV, and NPV, can be used to assess the reliability of a test. Sensitivity is defined as the percentage of people with the disease who are detected by the test. (It is calculated as the number of true-positive (TP) results divided by the sum of TP and false-negative [FN] results). Specificity is defined as the percentage of people without the disease who were correctly labeled by the test as not having the disease. (It is calculated as the number of true-negative (TN) results divided by the sum of the TN and false-positive [FP] results). Sensitivity and specificity are derived from patient populations in whom the true disease status is already known, who either all have or do not have the condition in question. These parameters provide data about how often the test will be positive or negative for these respective populations. Thus, these measures provide information about the test, because the disease status has already been determined in the patients. The PPV is defined as the likelihood that a patient with a positive test result actually has the disease. It is calculated as the number of TP results divided by the sum of the TP and FP results. The NPV is defined as the likelihood that a patient with a negative test result really does not have the disease. It is calculated as the number of TN results divided by the sum of the TN and FN results. Thus, these measures provide information about the disease. Both the PPV and the NPV vary with the prevalence of disease, which is the frequency of disease in the population, and they are calculated as the number of patients with either a TP or an FN result divided by the total number of patients. However, the impact of the prevalence on the NPV and the PPV is minor unless the prevalence is very high or low, respectively; therefore, the NPV (or PPV) from studies with $>80\%$ (or $<20\%$) prevalence are excluded from summary calculations. All these parameters are reported where appropriate.

1.2 Development and Grading of Recommendations

Recommendations were developed by the writing committee and were graded by a standardized method (described in detail by Lewis et al,[1] "Methodology for Development of Guidelines for Lung Cancer," in the ACCP Lung Cancer Guidelines). These were reviewed, revised, and eventually approved by all members of the lung cancer panel according to the standard process for these guidelines. After this, there were several additional levels of internal and external approval (the Thoracic Oncology NetWork, the Guidelines Oversight Committee, and the Board of Regents of the ACCP, as well as external reviewers and organizations), as described elsewhere.[1]

2.0 General Approach to Patients

The general approach to patients suspected of having lung cancer begins with a thorough history and physical examination. It is important to pay attention to both organ-specific (bone, brain) and nonspecific (fatigue, anorexia, weight loss) signs and symptoms of potential metastatic disease (Fig 1). The details of the clinical evaluation are discussed later, and were elucidated in detail in previous editions of the lung cancer guidelines.

Essentially, every patient suspected of having lung cancer should undergo a CT scan of the chest. This provides much information about the nature of the lesion seen on the chest radiograph or about the chest symptoms. The CT scan can either confirm the suspicion of lung cancer or raise suspicion of a different diagnosis. The radiographic appearance on a CT scan, together with appropriate risk factors, allows a clinical diagnosis of lung cancer to be made quite reliably by an experienced physician in the vast majority of patients (see Rivera et al,[5] "Establishing the Diagnosis of Lung Cancer," in the ACCP Lung Cancer Guidelines). This is an important step because it allows one to proceed with a thoughtful evaluation of the stage in most patients and to more efficiently establish both the diagnosis and the stage with one test, rather than pursue the diagnosis first, and then begin to consider the stage. Further details of chest imaging are covered in the section of this article on mediastinal staging.

Although a clinical evaluation may be reliable in some situations, further confirmation of the initial clinical stage is needed in many situations. In patients with a positive clinical evaluation and signs and symptoms of metastatic disease localized to a particular area, directed tests (plain bone films, needle aspiration [NA] of palpable lesions) may be sufficient to confirm the suspicion expediently. In patients with less localized or more subtle symptoms of possible distant metastases, imaging studies are needed. Finally, in most patients, further imaging is required even if the clinical evaluation is negative (Fig 2).[11-22] In particular, PET imaging has emerged as playing a prominent role, as discussed in the next section.

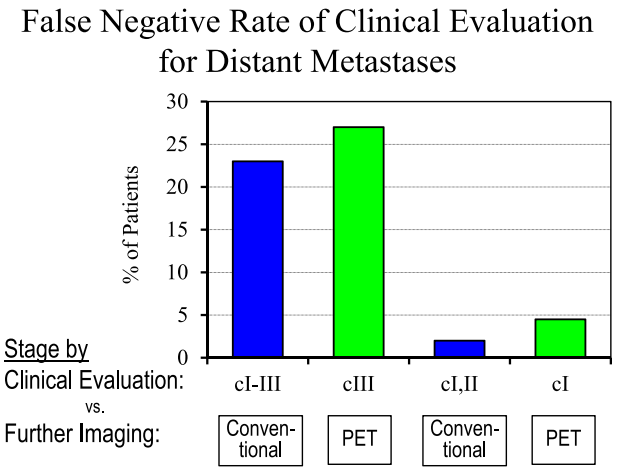
The chest CT scan is an important first step, not only to help define the clinical diagnosis, but to structure the subsequent staging and diagnostic evaluation. In general, patients with lung cancer can be separated into four categories with respect to intrathoracic radiographic characteristics (including both the primary tumor and the mediastinum), as shown in

Figure 1. [Section 2.0, 3.0] Clinical findings suggesting metastatic disease.

Component	Findings
Symptoms elicited in history	Constitutional: weight loss (>10 lb), anorexia, fatigue Musculoskeletal: focal skeletal pain Neurological: headaches, syncope, seizures, extremity weakness, recent changes in mental status
Signs found on physical examination	Supraclavicular lymphadenopathy (>1 cm) Hoarseness, superior vena cava syndrome Bone tenderness Hepatomegaly (>13-cm span) Focal neurologic signs, papilledema Soft-tissue mass
Routine laboratory tests	Hematocrit <40% in men, <35% in women Elevated alkaline phosphatase, GGT, AST, or calcium levels

AST = aspartate transaminase; GGT = γ-glutamyltransferase.

FIGURE 2. [Section 2.0, 3.0] False-negative rate of a negative clinical evaluation, as compared with either further PET imaging or conventional imaging (brain MRI/CT scan, abdominal CT scan, or ultrasound and bone scan). Rates are percentages of patients with a negative clinical evaluation in whom actual distant metastases are found upon further evaluation, averaged from all available studies that published stage-specific data: stage cI-III conventional[13,16-18,20]; cIII PET scan[11,15,22]; cI, II conventional[13,14]; cI PET scan.[15,19,21,22,192]. The clinical stage is that suggested by the negative clinical evaluation (ie, M0) and by the chest CT scan.



Figures 3 and 4. The first group (radiographic group A) involves patients with mediastinal infiltration that encircles the vessels and airways, so that the discrete lymph nodes can no longer be discerned or measured. The second group (radiographic group B) involves patients with mediastinal node enlargement, in whom the size of the discrete nodes can be measured. The last two groups involve patients with normal mediastinal nodes. In radiographic group C, the presence of a central tumor or suspected N1 disease makes the chance of N2,3 nodal involvement relatively high (20%-25%) despite normal-sized nodes, and further confirmation is needed.[23-26] In the final group (ie, those with a peripheral clinical stage I tumor), the chance of either distant metastases or mediastinal involvement is quite low (radiographic group D).[24-26]

PET imaging has emerged as a particularly useful test in a large proportion of patients with lung cancer. It can be used for multiple purposes, including to help confirm or render less likely a diagnosis of lung cancer, to detect extrathoracic metastases in patients who are asymptomatic or have subtle symptoms, to provide further information regarding the status of the mediastinum, and to provide an indication of the tumor's metabolic activity (as a predictor of biologic aggressiveness); it also has other treatment-related uses. PET scanning is usually performed for a combination of reasons. The amount of data supporting a role for PET scanning in patients with lung cancer has increased significantly since the previous guidelines, and the most relevant studies are summarized in the next section.

FIGURE 3. [Section 2.0, 4.1, 4.3] American College of Chest Physicians intrathoracic radiographic (CT scan) categories of lung cancer. A, Mediastinal infiltration by tumor. B, Enlarged discrete N2,3 nodes. C, A central tumor or a tumor with enlarged N1 nodes, but a normal mediastinum. D, A peripheral small tumor (seen in lower left corner of image) with normal-sized lymph nodes.

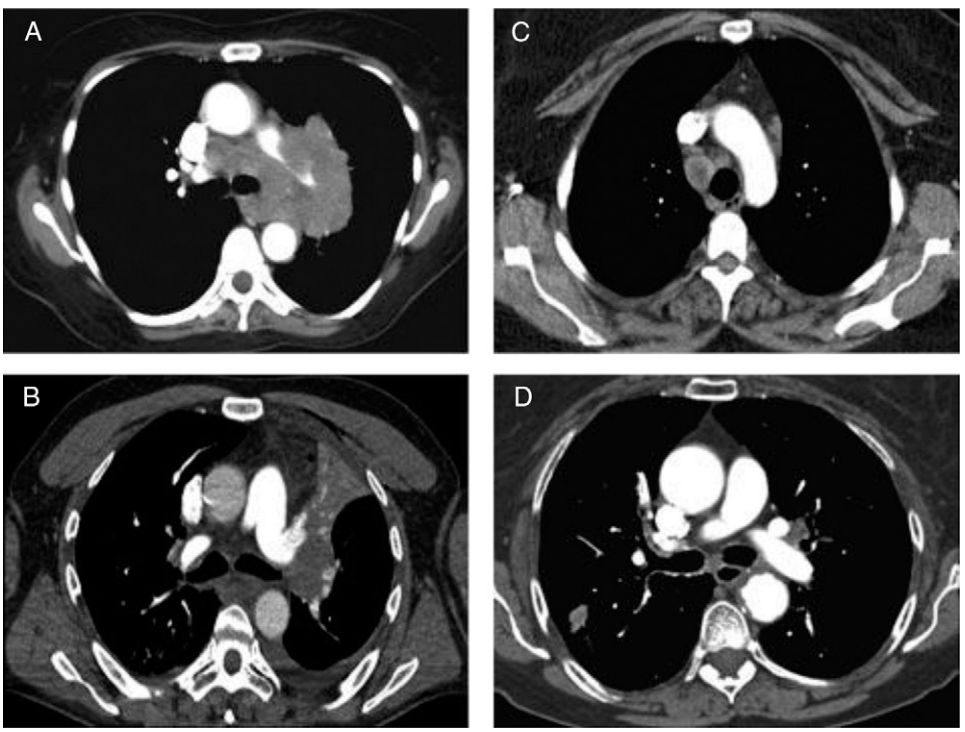


FIGURE 4. [Sections 2.0, 4.1] Definition of intrathoracic radiographic categories of lung cancer.

Group	Description	Definition (by chest CT scan)
A	Mediastinal infiltration	Tumor mass within the mediastinum such that discrete lymph nodes cannot be distinguished or measured[a]
B	Enlarged discrete mediastinal nodes	Discrete mediastinal nodes ≥ 1 cm in short-axis diameter on a transverse CT image
C	Clinical stage II or central stage I tumor	Normal mediastinal nodes (< 1 cm) but enlarged N1 nodes (≥ 1 cm) or a central tumor (within proximal one-third of the hemithorax)
D	Peripheral clinical stage I tumor	Normal mediastinal and N1 nodes (< 1 cm) and a peripheral tumor (within outer two-thirds of hemithorax)

[a]This does not include a tumor mass within the lung that is abutting the mediastinum and tangentially involving the mediastinal pleura or fat (this situation pertains to the T stage of the primary tumor and not the N stage of the mediastinum).

2.1 Recommendation

2.1.1. For patients with either a known or suspected lung cancer who are eligible for treatment, a CT scan of the chest with contrast is recommended (Grade 1B)**.**

Remark: If PET scan is unavailable for staging, the CT of the chest should be extended to include the liver and adrenal glands to assess for metastatic disease.

2.1.2. For patients with either a known or suspected lung cancer, it is recommended that a thorough clinical evaluation be performed to provide an initial definition of tumor stage (Grade 1B)**.**

2.1.3. In patients with either a known or suspected lung cancer who have an abnormal clinical evaluation and no suspicious extrathoracic abnormalities on chest CT, additional imaging for metastases is recommended (Grade 1B)**.**

Remark: Site specific symptoms warrant directed evaluation of that site with the most appropriate study.

2.2 Randomized Trials Involving PET Imaging

PET imaging plays a prominent role in the evaluation of patients with lung cancer, and the 2007 ACCP lung cancer guidelines recommended PET scans be performed in most patients. However, the situation is complex, because PET scans can provide information about the primary tumor, about the mediastinal lymph nodes, and about distant metastases. (PET scans can also provide information about the metabolic activity of the tumor, about the response to therapy, and for planning of radiotherapy treatment fields. However, these issues are not part of the stage evaluation and are not discussed in this article.) Furthermore, the contribution of PET scanning to the stage evaluation of patients is influenced by many factors, such as the likelihood that the patient has cancer, the likelihood that metastases are present, and to what extent the searching for metastases is accomplished by means other than PET scanning. Finally, PET scanning is not a definitive test, and tissue confirmation is often needed; how aggressively this is done also affects the impact PET scanning can have.

Five RCTs that evaluated the role of PET scanning in the evaluation of patients with lung cancer have been reported (Fig 5)[21,27-30] with somewhat different results. Given the fact that the impact of PET scanning involves a complex interplay of many factors, this should come as no surprise. This section summarizes these studies and discusses nuances to provide a better understanding of the factors involved, so that a thoughtful integration of PET scanning into patient management in particular settings can be accomplished.

Two RCTs of PET scanning found a marked benefit in terms of a reduction, from approximately 40% to 20%, in the number of noncurative resections performed (defined as the presence of benign disease, unsuspected N2 involvement, unresectable disease or recurrence, or death from any cause within 1 year).[27,30] One study found no difference in the rate of thoracotomy or incidence of distant metastatic disease.[21] Another study reported no difference in survival or the rate of thoracotomy, but found that PET scanning, as compared with conventional imaging, led to a higher rate of correctly identifying M1b disease (14% vs 7%), albeit at the minor expense of a higher rate of incorrect upstaging (5% vs 1%). In addition, the final pretreatment stage was less often understaged in the PET scan vs the conventional staging arm (15% vs 30%) when compared with subsequent events (ie, unsuspected pN2.3 or recurrence within 1 year). PET scanning, as compared with conventional imaging, also resulted in a lower rate of incorrectly understaging, albeit at the minor expense of a higher rate of incorrectly upstaging.[29] A final study focused on the number of tests needed to stage a patient with lung cancer and did not find a difference between

FIGURE 5. [Section 2.2] Randomized trials of PET scanning for staging lung cancer.

First Author	No.	Extent of Preenrollment Workup	Risk of Advanced Stage[a]	Thoroughness of Preoperative Staging[b]		% Having Surgery		% Noncurative Resection		% N2,3, M1 Identified Preoperatively		% M1 or Recurrence Within 1 y[c]	
				M1	% N2,3	Conv	PET	Conv	PET	Conv	PET	Conv	PET
Herder[28]	465	Minimal	++++	…	17	38	41	…	…	36	**34**	**2**[d]	4[d]
van Tinteren[30]	188	Minimal	+++	Low	69	81	65	41	21	12	**29**	**14**	4
Fischer[27]	189	Moderate	+++	Low	94	80	60	42	21	20	**37**	**19**	5
Maziak[29]	337	Moderate	++	High	51	78	81	…	…	14	**19**	**4**	8
Viney[21]	183	Good	+	High	5	98	96	…	…	1	**(5)**[e]	…	…

Inclusion criteria: randomized controlled trials of PET imaging in the pretreatment evaluation of patients with lung cancer.
Conv = conventional imaging (brain CT scan/MRI, abdominal CT scan/ultrasound, bone scan).
[a]Risk based on presence of clinical markers of advanced disease (> 5% weight loss, performance status ≥ 2).
[b]Extent of imaging for possible distant metastases and % of patients undergoing invasive mediastinal staging.
[c]Figures do not include noncancer deaths within 1 y.
[d]Within 6 mo.
[e]Reported rate of 5% reflects a policy of primary surgery despite the presence of N2 involvement; the rate would be approximately 15% if a policy of preoperative identification of N2,3 nodes were followed.

upfront PET scanning and conventional staging (average of 7.9 tests per patient in both arms).[28]

A closer look at the details of these studies reveals significant differences in the patients involved, the extent of preenrollment workup, the risk of advanced disease, and the extent of investigation for mediastinal and distant disease. For example, one study included patients referred by general practitioners on the basis of an abnormal chest radiograph only and the suspicion of lung cancer, with nearly one-third of patients having had >5% weight loss,[28] whereas another involved primarily patients with stage cI tumors (92%), as assessed by a thoracic surgeon, with histologic verification of lung cancer and brain and abdominal imaging in all.[21] In the first study,[28] which involved relatively limited investigation for distant and mediastinal metastases despite clinical findings indicating a high risk of metastases, PET scanning was clearly beneficial in identifying potential metastatic disease. The second study,[21] involving primarily patients with stage I disease and extensive imaging prior to randomization, found few distant metastases in either the PET scan or the conventional arm. Although in this study PET scanning correctly raised suspicion of N2 involvement, the surgical practice in this region was to nevertheless proceed with thoracotomy, without preoperative mediastinal staging, and thus, the rate of thoracotomy was not affected by PET imaging.

Those studies involving patients with a relatively high risk of advanced disease (frequent weight loss, poor performance status, and high rate of mediastinal node enlargement) have generally found that PET scanning increased the rate of preoperative detection of metastases and decreased the appearance of metastases during the following year. Furthermore, the studies with more thorough investigation of the mediastinum revealed a trend toward a higher rate of suspected N2.3 involvement through PET scanning. As the risk of advanced disease diminishes, and the extent of baseline staging evaluation increases, the impact of PET scanning appears to diminish.

Other population-based studies suggest that PET scanning has had a major positive impact on the stage classification of patients at a higher risk of having distant metastases. In the US national cancer database, as well as in the Surveillance, Epidemiology and End Results (SEER) registry, stage migration of a significant proportion of patients classified as stage III into stage IV has occurred, tracking with an increased use of PET scanning.[31,32] However, PET scanning appears to have little impact in patients with stage cI tumors.[31,33] A subset analysis of the patients with stage cI tumors in the American College of Surgeons Oncology Group PET scanning study found that PET scanning detected N2,3 or M1 involvement in 7% of patients

with stage cI tumors, but at a price of falsely suggesting N2,3/M1 disease in 14%.[34] Furthermore, although PET scanning had the potential to reduce the rate of biopsy for benign lesions from 21% to 11%, this would have come at the price of avoiding (or delaying) resection in 13% of cancers. The role of PET scanning is likely also limited in patients with ground-glass opacities with or without a solid component (but > 50% ground-glass opacities), although this is based on indirect arguments. These patients have a low rate of nodal involvement or distant metastases, making it unlikely that PET scanning would be of benefit (see the article on stage I, II NSCLC in the ACCP lung cancer guidelines).[35]

Overall, with PET scanning, about 20% more patients are correctly suggested as harboring distant or N2,3 metastases compared with conventional staging in the RCTs.[21,27,30] However, confirmation of PET scan findings is essential, because PET scanning also carries a significant rate of incorrect upstaging.[17] A potential harm of PET scanning is that if suspected PET scan findings are not confirmed, patients may be erroneously directed away from a potentially curative resection. In the RCTs involving PET scans, this would have occurred in 5% to 42% of patients; however, in these studies, the requirement of a definite confirmation of suspicious PET scan findings prevented this.[21,27,29,30] Although PET scanning clearly has the potential to be of benefit, in a less structured setting it also has the potential to be of harm if confirmation of the findings is not pursued.

Another potential issue is the type of PET scan and the setting in which it is performed, although there are few data to define the impact of this factor. Some of the RCTs of PET scanning for lung cancer evaluation involved an integral PET-CT scan, but in some others it was only PET scanning without CT scan correlation. These RCTs were conducted in organized health-care facilities, and generally relied on only one central PET scanner and interpretation despite involving many referral centers. The Canadian study is different in that it involved five PET scanners and eight centers.[29] However, the Canadian health-care system is still regionally well organized. This contrasts with the United States, in which care may be very decentralized, involving many smaller institutions and even mobile PET scanners. The ability to communicate clinical history, discuss interpretation, and provide feedback to radiologists in such a setting is much more challenging and likely affects the reliability of the interpretation. This underscores the need for confirmation of findings and for adaption of guidelines, such as those for PET scanning, to particular clinical settings. Nevertheless, the preponderance of data (including RCTs, prospective studies, and population studies) suggests that the PET scanning is much more of a benefit than a harm, and that this may be particularly true for physicians who have less clinical experience in treating lung cancer.

3.0 Extrathoracic Staging

The work-up of patients with newly diagnosed lung cancer should begin with a thorough clinical evaluation focusing on history, physical examination, and laboratory testing germane to patients with cancer. The current preferred "expanded" clinical evaluation includes organ-specific and constitutional signs and symptoms, along with simple laboratory tests, as shown in Figure 1.[36] It is well established that abnormal symptoms, physical findings, and routine blood tests in the initial clinical evaluation of patients with NSCLC are associated with a high likelihood of metastasis.[36] In addition, the NPV of the clinical evaluation (Fig 2)[11-22] is high enough in most circumstances to not warrant extrathoracic conventional scanning (bone scan, brain scan, and abdominal CT scan) if the clinical evaluation is negative (this recommendation does not apply to patients with clinical stage III and IV lung cancer, in which unsuspected metastases occur even with a negative clinical evaluation). Similarly, PET or PET-CT scanning has been found to be useful irrespective of the findings on the clinical evaluation.

The purpose of extrathoracic scanning in NSCLC is usually to detect metastatic disease, especially at common metastatic sites such as the adrenal glands, liver, brain, and skeletal system, thereby sparing the patient fruitless radical treatment.[4,36] However, scans can only detect macroscopic metastatic deposits that have reached a size within the resolution capability of a given imaging modality, and this can be considered a major shortcoming of all conventional tests currently used to detect distant metastases in NSCLC. The search for metastatic disease continues to evolve, with increased recognition of rapid dissemination in some patients with NSCLC. Mohammed et al[37] found that distant metastases may become evident on serial CT scans or PET scans in 3% of untreated patients at 4 weeks, in 13% at 8 weeks, and in 13% at 16 weeks, leading the authors to propose complete restaging after 4 to 8 weeks of delay. Most advances in the area of metastatic disease are the result of exploding interest in PET and PET-CT scans for staging and a host of additional possible clinical applications.

Current literature continues to demonstrate that PET and PET-CT scans are superior to conventional staging tests (bone scan and abdominal CT scan) in terms of performance characteristics. Specifically, PET scanning discloses previously unsuspected metastases in 6% to 37% of cases,[38-43] which results in more accurate TNM designation,[41] stage migration,[31,45] and

important changes in management,[46,47] including the indication for surgery.[41]

Recent data confirm the superiority of the performance characteristics of PET and PET-CT scans compared with conventional scans in the evaluation of metastatic disease in key specific distant sites. This concept is underscored by studies focusing on possible metastases to the adrenal glands,[48,49] liver,[50] and bone.[51] In addition, numerous reports document PET or PET-CT scan detection of unsuspected metastases to unusual distant sites such as the small bowel and skeletal muscle, thereby importantly changing the clinical stage and management of individual patients.[52-54]

The brain remains problematic because of the small size of most brain metastases, background brain F-fluoro-2-deoxy-D-glucose (FDG) uptake, and the variable biologic characteristics of brain metastases, which can be either hypermetabolic or hypometabolic.[55] However, in one series, the accuracy of integrated PET-CT scanning for brain metastases rivaled that of diagnostic brain CT scanning, and the need for a separate brain CT scan was obviated.[56] But, importantly, others have found that MRI improves detection when added to PET-CT scanning.[57] Biannual follow-up MRI may detect early brain metastases, thereby providing opportunities for radiosurgery.[58] Overall, it appears that the detection of brain metastases remains critical, and the detection of early metastases while still asymptomatic is increasingly important; treatment of such lesions is associated with better control of neurologic manifestations and longer survival.[59]

Since the publication of the last ACCP lung cancer guidelines, several studies have evaluated additional key outcomes related to PET and PET-CT scanning as staging modalities and have compared them with conventional staging (bone scan, abdominal CT scan). In general, these analyses suggest that PET scanning is cost effective compared with CT scanning[60] and correlates better with long-term outcomes.[61] Søgaard et al[62] found that PET-CT scanning increased cost by 3,927 Euros and that 4.92 PET-CT scans are needed to prevent one noncurative resection. Others also found decreases in unnecessary surgery when using PET or PET-CT scanning in the staging algorithm.[46,47,63,64]

Many other uses for PET scanning are emerging. The PET scan standard uptake value in the primary tumor may correlate with distant metastases[65] and help predict treatment response[66] and recurrences.[57] Dual-time PET scanning may be even more accurate in identifying malignant lesions.[67,68] PET scanning helps plan radiotherapy[69] and may reflect inhibition of glucose metabolism in chemotherapy-treated patients with NSCLC.[70-72]

Additional experience has underscored a few limitations of PET scanning. A PET scan-positive focus requires careful clinical correlation and biopsy confirmation if there is only one site of disease and if it changes the clinical stage. Verification bias can easily affect the sensitivity and specificity of PET scan-based tests when scan findings are not validated with tissue confirmation of the presence or absence of metastatic disease.[73] Lardinois et al[74] found that nearly one-half of the patients with NSCLC undergoing PET-CT scans with solitary extrapulmonary FDG accumulations had unrelated malignancies or benign disease at the solitary site in question. Overdiagnosis of nodal metastases can result in missed opportunities for surgical cure.[75] Incorrect upstaging was found in 4.8% of patients in Maziak's[29] series (compared with 0.6% in conventionally staged patients). Incorrect upstaging was equally likely in the mediastinum and in distant sites. Lung metastases (stage T4) were overlooked in 5% of subjects in one study using PET-CT scanning,[76] and understaging (30%) and overstaging (21%) were substantial concerns.

Finally, limited data are available comparing PET-CT scanning with PET scanning alone. In one retrospective study of 217 patients, PET-CT scanning was found to be significantly more accurate than PET or CT scanning alone.[77] A second retrospective study of 50 patients suggested that integrated PET-CT scanning is superior to PET scans, CT scans, and visually correlated separate PET and CT scans that are not coregistered.[44]

Several important caveats pertain to scanning for distant metastases in general. First is the issue of FP scans. Clinical entities that frequently give rise to FP scans include adrenal adenomas (present in 2%-9% of the general population), hepatic cysts, degenerative joint disease, old fractures, and a variety of nonmetastatic space-taking brain lesions. When clinically indicated, additional imaging studies and/or biopsies are performed to establish the diagnosis, but the complications and costs resulting from such subsequent investigations have received insufficient attention.[78,79]

3.1 Recommendations

3.1.1. In patients with a normal clinical evaluation and no suspicious extrathoracic abnormalities on chest CT being considered for curative-intent treatment, PET imaging (where available) is recommended to evaluate for metastases (except the brain) (Grade 1B)**.**

Remark: Ground glass opacities and an otherwise normal chest CT do not require a PET scan for staging.

Remark: In patients with peripheral stage cIA tumors a PET scan is not required.

Remark: If PET is unavailable, bone scan and abdominal CT are reasonable alternatives to evaluate for extrathoracic disease.

3.1.2. In patients with an imaging finding (eg, by PET) suggestive of a metastasis, further evaluation of the abnormality with tissue sampling to pathologically confirm the clinical stage is recommended prior to choosing treatment (Grade 1B)**.**

Remark: Tissue sampling of the abnormal site is imperative so that the patient is not excluded from potentially curative treatment.

Remark: Tissue sampling of a distant metastatic site is not necessary if there is overwhelming radiographic evidence of metastatic disease in multiple sites.

Remark: Tissue sampling of the mediastinal lymph nodes does not necessarily need to be performed if there is overwhelming radiographic evidence of metastatic disease in multiple distant sites.

3.2 Detection of Abdominal Metastases

In the past iteration of the guideline, 13 studies evaluated the usefulness of clinical evaluation in detecting abdominal metastases in 1,291 patients using CT scanning as the reference standard.[4] Most of the studies limited enrollment to patients with a negative clinical evaluation. The median predictive value of a negative clinical evaluation was 97% (82%-100%). The use of CT scanning as an imperfect reference standard suggests that these estimates should be interpreted with caution.

It is relatively common to encounter adrenal masses on a routine CT scan, but many of these lesions are unrelated to the malignant process. A unilateral adrenal mass in a patient with NSCLC is more likely to be a metastasis than a benign lesion according to some,[36,80] but not other, studies.[81,82] In the presence of clinical T1N0, NSCLC adenomas predominate,[83,84] whereas adrenal metastases are frequently associated with large intrathoracic tumors or other extrathoracic metastases.[36,85] Many studies suggest that the size of a unilateral adrenal abnormality on a CT scan is an important predictor of metastatic spread, but this is not a universal finding.[86]

PET scans have performed exceptionally well in several studies specifically addressing the problem of adrenal metastases in NSCLC, with accuracy as high as 100% in two studies.[87,88] However, small lesions (< 15 mm) were underrepresented in these series, and others have noted rare FPs in this site.[89-91] Four possible approaches to distinguishing between malignant and benign adrenal masses have been proposed: evaluation by specific CT scanning or MRI criteria, evaluation with additional or serial imaging, percutaneous biopsy, and adrenalectomy. Well-defined, low-attenuation (fatty) lesions with a smooth rim on an unenhanced CT scan are more likely to be benign adenomas,[92-94] but the CT scanning appearance of many lesions is insufficiently distinctive.[92] Follow-up scanning with repeat CT scans, serial ultrasounds, MRI (especially with chemical shift and dynamic gadolinium-enhanced techniques),[95] 131-6-betaiodomethylnorcholesterol scanning,[96] or PET scanning can often help distinguish metastatic disease from adenoma, which is critical. Percutaneous adrenal biopsy is a relatively safe and effective means of achieving a definitive diagnosis in doubtful cases and is especially important when the histology of the adrenal mass will dictate subsequent management.[97,98] However, this procedure may be nondiagnostic or unfeasible because of anatomic constraints. When insufficient material results from a biopsy, repeat aspiration or even adrenalectomy should be considered.[86,92]

Most liver lesions are benign cysts or hemangiomas, but contrast CT scanning (or ultrasound) is often required to establish a likely diagnosis.[99] Percutaneous biopsy can be performed when diagnostic certainty is required. One meta-analysis that specifically reviewed hepatic studies derived a pooled yield of 3% for liver metastases in asymptomatic patients with NSCLC.[79] PET scanning can detect liver metastases with an accuracy of 92% to 100% and there are only rare FPs, although data in NSCLC are very limited at present.[88,100]

3.3 Detection of Brain Metastases

In most studies, the yield of CT/MRI scanning of the brain in patients with NSCLC and negative clinical examinations is 0% to 10%.[101-107] In the last iteration of this guideline, 18 studies evaluated the ability of clinical evaluation to detect brain metastases in comparison with CT scanning in 1,830 patients.[4] These data were not updated in this iteration of the guideline. Nine studies limited enrollment to patients with a negative clinical evaluation. In these studies, the median prevalence of brain metastasis was 3% (range, 0%-21%), and the median predictive value of a negative clinical evaluation was 97% (range, 79%-100%). Nine other studies enrolled patients with both positive and negative clinical evaluations. In these studies, the median prevalence of brain metastasis was higher, at 14% (range, 6%-32%). Pooled sensitivity and specificity were 73% (95% CI, 60%-83%) and 85% (95% CI, 72%-92%), respectively.

An association among brain metastases, N2 disease in the chest, and adenocarcinoma histology has been described.[104,106,108] The FN rate of CT scanning (ie, where patients return with brain metastases within 12 months of the original scan) is reported to be 3%.[106] FP scans can be a problem in up to 11% of cases because of brain abscesses, gliomas, and other lesions[109]; therefore, biopsy may be essential in cases in which management is critically dependent on the histology of the brain lesion.

MRI is more sensitive than CT scanning of the brain and picks up more lesions and smaller lesions,[110] but in some studies, this has not translated into a clinically meaningful difference in terms of survival.[111] Although studies show that MRI can identify additional lesions in patients with metastases, the direct comparisons have not shown that MRI is able to identify more patients with metastases from lung cancer, compared with CT scanning. Therefore, CT scanning is an acceptable modality for evaluating patients for metastatic disease. In one study of 29 patients with NSCLC and a primary lesion >3 cm in size (ie, stage more advanced than T1N0M0), MRI with contrast identified asymptomatic, verifiable metastases to the brain in 22%.[112] However, to date, the use of routine MRI in staging patients with NSCLC and negative clinical evaluations has not been studied adequately; a role in patients with large cell carcinoma or stage III adenocarcinoma has been suggested.[113]

3.4 Recommendation

3.4.1. In patients with clinical stage III or IV NSCLC it is suggested that routine imaging of the brain with head MRI (or CT if MRI is not available) should be performed, even if they have a negative clinical evaluation (Grade 2C)**.**

3.5 Detection of Bone Metastases

The problem of FP scan abnormalities in radionuclide bone scintigraphy is particularly nettlesome, owing to the frequency of degenerative and traumatic skeletal damage and the difficulty in obtaining a definitive diagnosis via follow-up imaging or biopsy. FP bone imaging also occurs with MRI, which may be no more accurate than nuclear bone imaging.[112] Eight studies examined the ability of clinical evaluation to detect bone metastases in 723 patients, using bone scanning as the reference standard.[4] Two studies limited enrollment to patients with negative clinical evaluations.[114,115] Using radionuclide bone scanning as the reference standard, the pooled negative predicted value of the clinical assessment was 90% (95% CI, 86%-93%). PET scanning appears to have excellent performance characteristics in assessing bone metastases, with specificity, sensitivity, NPV, PPV, and accuracy all exceeding 90%,[88,116] although FP and FN findings are seen occasionally.[19,88,91] The accuracy of PET scanning surpassed that of radionuclide bone scanning in two direct comparative studies.[117,118]

3.6 Pleural Effusions/Lung Metastases

Limited data suggest that PET scanning can be useful in identifying lung metastases[88,119] and malignant pleural effusions in NSCLC,[120,121] although much of the data pertains to nonpulmonary malignancies. FPs and FNs are noted occasionally.[90,120,122]

4.0 Staging of the Mediastinum

4.1 General Concepts

Staging is a critical part of the evaluation of every patient with lung cancer. Defining malignant involvement of the mediastinal lymph nodes is particularly important, because in many cases, the status of these nodes determines whether there is surgically resectable disease. Clinical staging of lung cancer is usually directed by noninvasive imaging modalities. On the basis of such tests, physicians determine the likelihood of the presence or absence of tumor involvement in regional lymph nodes.

In general, patients with lung cancer can be separated into four groups with respect to intrathoracic radiographic characteristics (including both the primary tumor and the mediastinum), as shown in Figures 3 and 4. Distinguishing these groups is particularly useful in defining the need and selection of invasive staging tests. The first group (radiographic group A) involves patients with mediastinal infiltration that encircles the vessels and airways, so that discrete lymph nodes can no longer be discerned or measured. In these situations, the presence of mediastinal involvement (stage III) is generally accepted based on imaging alone, and the major issue is to obtain tissue by whatever approach is easiest, to distinguish between SCLC and NSCLC. However, in such patients, sampling the mediastinum can often confirm both the stage of disease and the diagnosis with minimal, if any, additional risk, compared with sampling the primary tumor alone. The second group (radiographic group B) involves patients with mediastinal node enlargement, in whom the size of discrete nodes can be measured. In these patients, mediastinal nodal involvement is suspected but must be confirmed. The last two groups involve patients with mediastinal nodes that are not enlarged. In radiographic group C, the presence of a central tumor or suspected N1 disease makes the chance of N2,3 nodal involvement relatively high (20%-25%) despite normal-sized nodes, and further confirmation is needed.[24-26,123] In the final group (ie, those with a peripheral clinical

stage I tumor), the chance of mediastinal involvement is quite low, and, generally, further confirmation of this is not needed (radiographic group D).[24-26]

A widely accepted definition of normal-sized mediastinal lymph nodes is a short-axis diameter of ≤ 1 cm on a transverse CT scan image. Discrete nodal enlargement implies that discrete nodes are seen on the CT scan and are defined well enough that their size can be measured (and are > 1 cm). Mediastinal infiltration is present when there is abnormal tissue in the mediastinum that does not have the appearance and shape of distinct lymph nodes but instead, has an irregular, amorphous shape. In this case, it is difficult to distinguish discrete nodes and impossible to come up with a measurement of the size of the nodes. This occurs when multiple nodes are matted together to the point at which the boundary between them is obscured and it can be assumed that extensive extranodal spread of the tumor is involved. It may progress to the point where mediastinal vessels and other structures are partially or completely encircled. Finally, the distinction between a central and a peripheral tumor has also not been codified, but most authors consider any tumor in the outer two-thirds of the hemithorax to be peripheral. Assessing the radiographic characteristics of the mediastinum generally requires that the physician look at the images himself or herself because there is no standard format defining how radiographic findings are reported (eg, the term "lymphadenopathy" is often used when there is a suspected malignancy even though the mediastinal nodes are well below 1 cm in size).

The four radiographic groups are defined by anatomic characteristics on a CT scan (ie, size, location, extent), and not by metabolic characteristics (ie, PET scan) for many reasons. First, a CT scan is relatively inexpensive and essentially is always done as a preliminary step to define the nature of a pulmonary abnormality and arrive at a clinical diagnosis of suspected lung cancer. Second, the information gained from the clinical history, physical examination, and chest CT can determine whether other tests, such as a PET scan, are indicated. Finally, the technical considerations and performance characteristics of invasive staging procedures are likely to be driven primarily by anatomic characteristics rather than metabolic ones. In other words, the location and size of a lymph node are important in determining how feasible and reliable an invasive test is, and these issues are unaffected by whether or not the node in question is metabolically active on PET scan.

4.2 Imaging Studies

4.2.1 Chest Radiographs: The majority of lung cancers are detected initially by plain chest radiograph, although this has likely changed in recent years with the increasing use of chest CT scanning for a myriad of indications. In some situations, the plain film may be sufficient to detect spread to the mediastinum. For example, the presence of bulky lymphadenopathy in the superior or contralateral mediastinal areas may be considered adequate evidence of metastatic disease, precluding further imaging evaluation of the chest. This may be particularly true if the patient is too ill or unwilling to undergo treatment of any kind. However, it is recommended that tissue confirmation be obtained if possible by the least invasive method available. It is widely accepted that the chest radiograph is, in general, an insensitive measure of mediastinal lymph node involvement with lung cancer, and thus, further noninvasive and/or invasive assessment is usually necessary.

4.2.2 CT Scanning of the Chest: CT scanning of the chest is the most widely available and most commonly used noninvasive modality for evaluation of the mediastinum in lung cancer. The vast majority of reports evaluating the accuracy of CT scanning for mediastinal lymph node staging have employed the administration of IV contrast material. IV contrast is not absolutely necessary in performing chest CT scans for this indication but it may be useful in helping distinguish vascular structures from lymph nodes, as well as in delineating mediastinal invasion by centrally located tumors. Experienced chest radiologists can usually make this distinction with respect to mediastinal nodes, provided the scan was performed with appropriately thin sections (≤ 5 mm), but identification of N1 nodes and the relationship to central pulmonary vessels remains an issue. A CT scan of the chest should be performed in all cases of lung cancer unless the patient is so debilitated that no treatment is planned or he/she is unwilling to undergo further evaluation.

Various CT scanning criteria have been used to define malignant involvement of mediastinal lymph nodes. Notwithstanding the radiographic descriptions of mediastinal nodal involvement, the most widely used criterion is a short-axis lymph node diameter of ≥ 1 cm on a transverse CT scan. However, numerous other criteria have also been used, including (1) long-axis diameter ≥ 1 cm, (2) short-axis diameter ≥ 1.5 cm; (3) short-axis diameter ≥ 1 cm plus evidence of central necrosis or disruption of the capsule; and (4) short-axis diameter ≥ 2 cm regardless of nodal morphology. The reported sensitivity and specificity for identifying malignant involvement will vary depending on which criteria are used in the assessment of individual nodal stations.[124,125] The majority of studies evaluating CT scan accuracy have used short-axis ≥ 1 cm as the threshold for abnormal nodes. In doing

so, a conscious effort has been made to strike an appropriate balance between sensitivity and specificity in an understandable effort to minimize the number of FP evaluations without producing an unacceptable number of FN evaluations.

For the purposes of these guidelines, three authors of this section (G. S., A. G., M. J. G.) conducted a systematic review of the medical literature relating to the accuracy of CT scanning for noninvasive staging of the mediastinum in lung cancer and updated the data using the methods from previous guidelines.[4,10] When combined with the previous iterations of these guidelines, the combined studies yielded 7,368 evaluable patients (Fig 6).[19,24,44,47,88,90,126-162] The median prevalence of mediastinal metastasis was 30%. Almost all studies specified that CT scanning was performed following administration of IV contrast, and that a positive test result was defined as the presence of one or more lymph nodes that measured > 1 cm in short scanning axis diameter. The median sensitivity and specificity of CT scanning for identifying mediastinal lymph node metastasis were 55% and 81%, respectively. CT scanning has limited ability to either rule in or exclude mediastinal metastasis. The combined estimates should be interpreted with caution because the studies were statistically heterogeneous. Still, these findings mirror those of other analyses addressing the accuracy of CT scanning for staging of the mediastinum in NSCLC[163,164] and are similar to the last iteration of this guideline.[4]

CT scanning is clearly an imperfect means of staging of the mediastinum, but it remains the best overall anatomic study available for the thorax. CT scanning usually guides the choice of nodes for selective node biopsy by invasive techniques, and thus continues to be an important diagnostic tool in lung cancer. The choice of individual nodes for sampling, as well as the choice of the most appropriate invasive technique (including transbronchial, transthoracic, or transesophageal NA; mediastinoscopy; or more extensive surgery), are typically directed by the findings of the CT scan. However, the limitation of CT scan-based mediastinal lymph node evaluation is evident in the fact that 5% to 15% of patients with clinical T1N0 (clinical stage IA) tumors are found to have positive lymph node involvement by surgical lymph-node sampling.[99]

Based on the currently available data relating to the performance characteristics of CT scanning for the evaluation of the mediastinum in NSCLC, two important messages emerge. First, an unacceptably high percentage of lymph nodes deemed malignant by CT scan criteria are actually benign. Second, a significant number of lymph nodes deemed benign by CT scan criteria are actually malignant. Chest CT scans can both overstage and understage the mediastinal nodes. In sum, there is no node size that can reliably determine stage and operability. In cases in which the CT scan criteria for identification of a metastatic node are met, the physician must still prove by biopsy that the node is indeed malignant. Given the limitations of its imperfect sensitivity and specificity, it is usually inappropriate to rely solely on the CT scan to determine mediastinal lymph node status in NSCLC. Nonetheless, CT scanning continues to play an important and necessary role in the evaluation of these patients. In the mediastinum, CT scanning can provide a road map that guides the physician to the location and modality for subsequent biopsy procedures.

FIGURE 6. [Section 4.2.2] Accuracy of CT scanning for staging of the mediastinum in patients with lung cancer.

First Author	Year	No.	Tech	Prev	Sens	Spec	PPV	NPV
Eggeling[137]	2002	73	CE	70	82	50	79	55
Wallace[143]	2001	121	CE	69	87	35	75	54
Marom[88]	1999	79	CE	56	59	86	84	63
Vansteenkiste[150]	1998	56	CE	50	86	79	80	85
Aaby[156]	1995	57	…	44	72	91	86	81
Schillaci[136]	2003	83	CE	42	69	75	67	77
Vansteenkiste[151]	1998	68	CE	41	75	63	58	78
Primack[157]	1994	159	CE	38	63	86	73	79
Turkmen[130]	2007	59	CE	36	43	66	41	68
Laudanski[141]	2001	92	CE	33	60	73	51	79
Yokoi1[58]	1994	113	CE	33	62	80	61	81
Gdeedo[153]	1997	100	CE	32	63	57	41	76
Bury[155]	1996	53	CE	32	71	81	63	85
McLoud[159]	1992	143	CE	31	64	62	44	79
Pieterman[90]	2000	102	CE	31	75	66	50	85
Yen[127]	2008	96	CE	31	47	80	52	77
Osada[146]	2001	335	CE	30	56	93	77	83
Jolly[160]	1991	336	CE	30	71	86	69	87
Subedi[47]	2009	91	CE	29	50	86	59	81
Buccheri[154]	1996	80	CE	28	64	74	48	84
Pozo-Rodriguez[24]	2004	132	CE	27	86	67	49	93
Kiernan[138]	2002	92	CE	27	64	94	80	88
Reed[19]	2003	302	CE	25	37	91	58	81
Nosotti[139]	2002	87	CE	25	64	88	64	88
Dunagan[144]	2001	72	CE	25	50	87	56	84
Kimura[135]	2003	203	CE	24	63	97	88	89
Yi1[29]	2007	143	CE	24	65	89	65	89
Suzuki[149]	1999	440	CE	23	33	92	56	82
Bury[152]	1997	64	CE	22	79	84	58	93
De Wever[44]	2007	50	CE	22	91	72	48	97
Webb[162]	1991	154	CE	21	52	69	31	84
Cole[161]	1993	150	…	21	26	81	26	81
Takamochi[132]	2005	71	CE	21	20	89	33	81
Kamiyoshihara[145]	2001	546	CE	20	33	90	46	84
Takamochi[147]	2000	401	CE	20	30	82	30	83
Lee[126]	2009	182	CE	20	36	79	30	83
Yang[128]	2008	122	CE	20	52	73	33	86
Kelly[134]	2004	69	CE	19	46	86	(43)[a]	87
Saunders[148]	1999	84	…	18	20	90	(30)[a]	84
Nomori[133]	2004	80	…	18	50	95	(70)[a]	90
Ebihara[131]	2006	205	CE	15	32	83	(26)[a]	87
Poncelet[142]	2001	62	CE	15	56	68	(23)[a]	90
Von Haag[140]	2002	52	CE	12	50	65	(16)[a]	91
Median: prevalence > 30					**67**	**74**	**62**	**79**
Median: prevalence 21-30					**63**	**87**	**58**	**84**
Median: prevalence ≤ 20					**41**	**83**	**30**	**87**
Summary: Median		**7,368**		**30**	**55**	**81**	**58**	**83**

Inclusion criteria: studies reporting test characteristics of chest CT scanning to identify benign or malignant mediastinal nodes in patients with lung cancer, involving ≥ 50 patients from 1980 to 2011. CE = contrast enhanced; NPV = negative predictive value; Prev = prevalence; PPV = positive predictive value; Sens = sensitivity; Spec = specificity; Tech = technical details of imaging.

[a]Because PPV is increasingly affected by prevalence as prevalence is < 20% these values are excluded from summary calculations.

4.2.3 PET Scanning: PET scanning is an imaging modality based on the biologic activity of neoplastic cells. Lung cancer cells demonstrate increased cellular uptake of glucose and a higher rate of glycolysis when compared with normal cells.[165] The radio-labeled glucose analog[157] F-fluoro-2-deoxy-d-glucose (FDG) undergoes the same cellular uptake as glucose, and is phosphorylated by hexokinase, generating FDG-6-phosphate. The combination of increased uptake of FDG and a decreased rate of dephosphorylation by glucose-6-phosphatase in malignant cells results in an accumulation of FDG-6-phosphate in these cells.[166,167] The accumulated isotope can then be identified using a PET scan camera. FDG-PET scanning (subsequently referred to as PET scanning) is thus a metabolic imaging technique based on the function of a tissue rather than its anatomy. Standardized quantitative criteria for an abnormal PET scan in the mediastinum are unfortunately lacking. A qualitative assessment is usually based on a comparison of uptake in the lesion or structure in question and the background activity of the lung or liver. A standard uptake value of >2.5 is sometimes used as a threshold level for malignancy, but this value is based on the uptake of peripheral masses >2 cm; the applicability to mediastinal nodes is questionable at best. Despite the lack of standardized criteria defining positive findings, PET scanning has proved useful in differentiating neoplastic from normal tissues. However, the technique is not infallible because nonneoplastic processes including granulomatous and other inflammatory diseases, as well as infections, may also demonstrate positive PET imaging findings. Further, size limitations are an issue, with the lower limit of spatial resolution of current generation PET scanners being approximately 7 to 10 mm. Nevertheless, smaller lesions may be detected, depending on the intensity of uptake of the isotope in abnormal cells.[90,168] Additionally, certain well-differentiated low-grade malignancies, particularly adenocarcinoma in situ, well-differentiated invasive adenocarcinomas, and typical carcinoid tumors, are known to have a higher risk of FN results.[169-173]

A burgeoning number of studies in the past several years have reported on the use of PET scanning in the assessment of the mediastinum in patients with lung cancer. Increasing availability of the technology now allows PET scanning to be used widely as a diagnostic tool. It has already been noted that PET scanning is primarily a metabolic examination and has limited anatomic resolution. It is usually possible to identify lymph node stations, but not individual lymph nodes, by PET scanning. CT scanning provides much more anatomic detail, but lacks the functional information provided by PET scanning.

As was done for CT scanning, the authors of this article updated the 2003 and 2007 guidelines by performing a systematic review of the medical literature relating to the accuracy of PET scanning for noninvasive staging of the mediastinum in lung cancer, using the methods described previously.[4,10] All studies were either combined PET-CT scans or were interpreted in conjunction with patients' CT scans so that the findings on PET scanning were correlated with the anatomic location of the lesion on CT scanning. In all studies, FDG was the radiopharmaceutical used for imaging. A total of 4,105 patients were included in this evaluation (Fig 7).* The median prevalence of mediastinal metastasis was 28%. The median sensitivity and specificity for identifying mediastinal metastasis were 80% and 88%, respectively. These findings demonstrate that PET scanning is more accurate than CT scanning for staging of the mediastinum in lung cancer, although it is not perfect.

An important shortcoming of dedicated PET imaging is its limited spatial resolution, which results in poor definition of anatomic structures. As a result, it may be difficult to use PET scans to distinguish between mediastinal and hilar lymph nodes, or to differentiate between a central primary tumor and a lymph node metastasis, even when the results of PET and CT scanning are correlated visually. This limitation has been addressed by the development of "dual-modality" or "integrated" PET-CT scanning systems, in which a CT scanner and PET scanner are combined in a single gantry. Since the last iteration of these guidelines, more studies evaluating the accuracy of integrated PET-CT scanners for lung cancer staging have been performed. For this iteration of the guidelines, we have separated studies that used PET scanning alone from those that used PET-CT scanning.[150,151,196-198] From 2000 to 2111, a total of 19 studies were identified that included 2,014 patients who met the inclusion criteria and underwent PET-CT scanning; the results of these 19 studies are displayed in Figure 8.[29,40,44,47,76,126,128,129,199-209] Although the specificity of this technique was slightly higher than with PET scanning alone, the sensitivity was significantly lower. The reason for this is unclear.

PET scanning is less sensitive for lymph nodes with diameters <7 to 10 mm, and most of the invasive technologies (mediastinoscopy, endobronchial ultrasound [EBUS], and endoscopic ultrasound [EUS]) have discovered unsuspected mediastinal metastases in patients with normal-sized lymph nodes without PET scanning activity.[210,211] The clinical presentation in which controversy can arise is the patient with a peripheral clinical T1a lesion (small pulmonary nodule) who has normal-sized lymph nodes without PET scanning avidity, particularly if the density of

*References 12,19,24,26,40,64,88,90,127,130-134,138,140,142,144,148,150-152,155,174-195.

FIGURE 7. [Section 4.2.3] Accuracy of PET scanning for staging of the mediastinum in patients with lung cancer.

First Author	Year	No.	Prev	Sens	Spec	PPV	NPV
Changlai[185]	2001	127	64	88	83	90	79
Marom[88]	1999	79	56	73	94	85	88
Bury[155]	1996	30	53	88	86	88	86
Vansteenkiste[150]	1998	56	50	86	43	60	75
Sazon[192]	1996	32	50	100	100	100	100
Nosotti[64]	2008	413	48	97	97	97	97
Fritscher-Ravens[179]	2003	33	48	75	88	86	79
Wahl[195]	1994	23	48	82	75	75	82
Tatsumi[186]	2000	21	48	80	82	80	82
Guhlmann[190]	1997	32	47	87	100	100	89
Verhagen[26]	2004	56	46	58	90	83	71
Vansteenkiste[151]	1998	68	41	93	95	93	95
Vesselle[184]	2002	118	36	81	96	92	90
Turkmen[130]	2007	59	36	76	79	67	86
Zimny[182]	2003	33	36	83	81	71	89
Liewold[187]	2000	78	35	93	78	69	95
Scott[193]	1996	27	33	100	100	100	100
Magnani[189]	1999	28	32	67	84	67	84
Pieterman[90]	2000	102	31	91	86	74	95
Yen[127]	2008	96	31	73	92	81	88
Chin[194]	1995	30	30	78	81	64	89
Demura[178]	2003	50	30	87	63	50	92
Steinert[191]	1997	47	28	92	97	92	97
Melek[175]	2008	170	28	75	68	48	87
Kiernan[138]	2002	88	28	88	86	71	95
Halpern[177]	2005	36	28	50	77	45	80
Pozo-Rodriguez[24]	2005	132	27	81	76	56	91
Dunagan[144]	2001	81	26	52	88	61	84
Reed[19]	2003	302	25	61	84	56	87
Bernasconi[176]	2006	51	25	54	76	44	83
Roberts[188]	2000	100	24	88	91	75	96
Gonzalez-Stawinski[180]	2003	202	23	66	78	48	88
Bury[152]	1997	64	22	86	100	100	96
Takamochi[132]	2005	71	21	40	88	46	84
Saunders[148]	1999	84	20	71	97	86	93
Kernstine[183]	2002	237	19	82	82	51	95
Kelly[134]	2004	69	19	62	98	(89)[a]	92
Nomori[133]	2004	80	18	86	97	(86)[a]	97
Lee[40]	2007	210	17	61	94	(69)[a]	92
Ebihara[131]	2006	205	15	74	90	(58)[a]	95
Poncelet[142]	2001	61	15	67	85	(43)[a]	94
Von Haag[140]	2002	52	12	67	91	(50)[a]	95
Yamamoto[174]	2008	34	9	33	84	(17)[a]	93
Konishi[181]	2003	54	9	80	92	(50)[a]	98
Farrell[12]	2000	84	5	100	93	(40)[a]	100
Median: prevalence > 30				**85**	**87**	**84**	**88**
Median: prevalence 21-30				**77**	**83**	**56**	**89**
Median: prevalence ≤ 20				**71**	**92**	**51**	**95**
Summary: median		**4,105**	**28**	**80**	**88**	**75**	**91**

Inclusion criteria: studies reporting test characteristics of PET scanning to identify benign or malignant mediastinal nodes in patients with lung cancer, involving ≥ 20 patients from 1980 to 2011. See Figure 4 legend for expansion of abbreviations.

[a]Because PPV is increasingly affected by prevalence as prevalence is < 20% these values are excluded from summary calculations.

the nodule is ground glass (ie, not solid). On the one hand, confirmation of the negative PET scan findings by any of the invasive staging methods may not be necessary because the incidence of this clinical situation of mediastinal nodal metastases is so low (although not zero) as to not warrant the test.[34] Conversely, approximately 4% of patients with stage I disease have unsuspected mediastinal disease, discovered in those patients with a radiographically and PET scan-normal mediastinum.[210,211] Ultimately, the decision as to whether a negative PET scan can be used to obviate invasive staging preoperatively requires clinical judgment that incorporates multiple factors, including the clinical pretest probability of mediastinal metastasis, patient preferences, and local availability and expertise in both invasive procedures and PET imaging.

FIGURE 8. [Section 4.2.3] Accuracy of integrated PET-CT scanning for staging of the mediastinum in patients with lung cancer.

First Author	Year	No.	Prev	Sens	Spec	PPV	NPV
Cerfolio[200]	2004	40	100	75	…	…	…
Plathow[204]	2008	52	73	100	100	100	100
Fischer[361]	2011	79	33	85	100	100	93
Lee[202]	2009	41	32	38	89	63	76
Yi[209]	2008	150	30	62	94	82	85
Maziak[29]	2009	167	29	48	93	74	82
Subedi[47]	2009	91	26	92	85	69	97
Yi[129]	2007	143	24	56	100	100	88
Carnochan[76]	2009	194	23	42	87	50	83
Lee[40]	2007	126	22	86	81	56	95
De Wever[44]	2007	50	22	73	82	53	91
Lee[126]	2009	182	20	81	73	42	94
Yang[128]	2008	122	20	52	73	33	86
Perigaud[203]	2009	51	20	40	85	40	85
Billé[199]	2009	159	19	48	93	(63)[a]	88
Toba[207]	2010	42	19	100	88	(67)[a]	100
Usuda[208]	2011	63	17	36	92	(50)[a]	87
Sanli[205]	2009	78	14	82	90	(56)[a]	97
Shin[206]	2008	184	13	48	95	(58)[a]	93
Summary: median		**2,014**	**22**	**62**	**90**	**63**	**90**

Inclusion criteria: studies reporting test characteristics of integrated PET-CT scanning to identify benign or malignant mediastinal nodes in patients with lung cancer, involving ≥ 20 patients from 2000 to 2011. See Figure 6 for expansion of abbreviations.

[a]Because PPV is increasingly affected by prevalence as prevalence is < 20% these values are excluded from summary calculations.

A recent phenomenon with regard to PET scanning is that published studies often assess the usefulness of PET scanning as it relates to a single aspect of the patient's presentation (eg, solitary pulmonary nodule, mediastinal disease, or distant metastatic disease) and they often find flaws in the technology as it relates to the specific indication for which the study was undertaken. However, the physician does not view a PET or PET-CT scan in a vacuum; these studies often provide information about the primary site of the tumor in the chest as well as intrathoracic and extrathoracic metastases. The resultant information can lead the physician to undertake a biopsy of a different area than the one initially anticipated by CT scan, which often provides more accurate staging, especially when unsuspected metastatic disease is discovered by PET scanning.

To summarize, PET scanning has both higher sensitivity and higher specificity than CT scanning for the evaluation of mediastinal lymph nodes and can provide important information regarding the presence of metastatic disease outside the thorax. In the mediastinum, PET scanning is more accurate than CT scanning in identifying abnormal nodes that can be sampled by directed biopsy. Accordingly, PET scanning has assumed an increasingly important role in the evaluation of patients with lung cancer, although this technology is not infallible. FP PET scan findings may result in missed opportunities for cure by surgical resection. Conversely, FN PET scan findings may lead to noncurative resection. The potential consequences of both FP and FN PET scan findings in an environment in which PET scanning is increasingly

relied on for staging must be considered when PET scanning is included in the evaluation of NSCLC. One should not preclude a potential curative surgery based on a positive PET scan alone without tissue confirmation. However, PET scanning is the most accurate noninvasive imaging modality available to evaluate the mediastinum in patients with lung cancer. PET scanning is also a whole-body study (excluding the brain), offers additional information relating to extrathoracic sites of possible disease involvement, and can reduce noncurative resections. PET scanning has now assumed a central role in the staging of lung cancer.

4.2.4 MRI: Like CT scanning, MRI is an anatomic study. Data relating to the accuracy of the evaluation of the mediastinum in patients with NSCLC with MRI are limited, but available reports suggest that the accuracy of MRI is as good as that of CT scanning.[162,212] Two reports also suggest that the use of contrast enhancement may improve the accuracy of MRI in this situation.[212,213] MRI may be superior to CT scanning in defining lung cancer spread in the thorax in specific situations. Because MRI can detect differences in intensity between tumor and normal tissues, including bone, soft tissues, fat, and vascular structures, it may be more accurate than CT scanning in delineating direct tumor invasion of the mediastinum, chest wall, diaphragm, or vertebral bodies.[162,214-217] This may be particularly useful in evaluating superior sulcus tumors or tumors abutting the mediastinum, structures of the chest wall, and diaphragm. However, most centers continue to rely on CT scanning as the noninvasive anatomic study of choice for evaluating the potential mediastinal spread of lung cancer. In summary, an MRI of the chest should not be performed routinely for staging of the mediastinum. MRI is useful in patients with NSCLC when there is concern about involvement of the superior sulcus or the brachial plexus.

4.3 Invasive Techniques to Stage the Mediastinum

After performing the initial imaging studies, the physician selects his or her next test based on the radiographic presentation (see radiographic groups mentioned previously and Fig 3) and local availability and expertise of the physicians performing these procedures. The separation into radiographic groups helps guide the choice of invasive test and the performance characteristics of these tests. The radiographic groups are defined by anatomic characteristics on a CT scan for several reasons. First, a CT scan is relatively inexpensive and is always done as a preliminary step to define the nature of a pulmonary abnormality and arrive at a clinical diagnosis of suspected lung cancer. Second, the technical reasons for choosing one invasive approach over another are governed primarily by anatomic factors (ie, the location and size of the nodes) rather than by metabolic factors (ie, PET scan uptake).

Interpretation and application of the results of invasive staging procedures are difficult because the published data are defined by patients who have undergone a particular test, rather than by radiographic or clinical criteria that could be used prospectively to select patients for a particular approach. The patients who have undergone a particular procedure are a mix of the different radiographic groups just discussed and often include patients in whom the primary issue was confirmation of the diagnosis, those in whom it was confirmation of nodal involvement, and those in whom it was confirmation of a lack of nodal involvement. Furthermore, the location of the suspected nodal involvement influences which test is performed because some nodal stations are easily accessible by one test and not by another. Therefore, the patient cohorts included in the series of particular invasive procedures are likely not the same. This makes comparison of sensitivity and specificity of the different tests inappropriate. In addition, operator experience is very likely to affect the performance characteristics of a procedure and must also be taken into account in choosing an invasive staging procedure in a specific practice setting. At any rate, it is best to view the different imaging and invasive staging tests as complementary and not competitive.

4.3.1 Surgical Staging:

4.3.1.1 Mediastinoscopy—Mediastinoscopy is performed in the operating room, usually under general anesthesia, and in most US centers, patients are discharged the same day.[218-220] The procedure involves an incision just above the suprasternal notch, insertion of a mediastinoscope alongside the trachea, and biopsy of mediastinal nodes. Rates of morbidity and mortality as a result of this procedure are low (2% and 0.08%).[221] Right and left high and low paratracheal nodes (stations 2R, 2L, 4R, 4L), pretracheal nodes (stations 1, 3), and anterior subcarinal nodes (station 7) are accessible via this approach. Node groups that cannot undergo a biopsy with this technique include the posterior subcarinal (station 7) nodes, the inferior mediastinal (stations 8, 9) nodes, the aortopulmonary window (APW) (station 5) nodes, and the anterior mediastinal (station 6) nodes. A videomediastinoscope allows better visualization, more extensive sampling (including posterior station 7), and even the performance of a lymph node dissection.[222,223]

As was done for the noninvasive tests, the authors, using previously described methodology, updated the 2003 and 2007 guidelines by performing a systematic

review of the medical literature relating to the accuracy of mediastinoscopy for staging of the mediastinum in lung cancer.[3,10] The median sensitivity of standard cervical mediastinoscopy to detect mediastinal node involvement from cancer was 78% in 9,267 patients (Fig 9).[125,156,160,222,224-245] The median NPV was 91%. Several authors have shown that approximately one-half (42%-57%) of the FN cases were due to nodes that were not accessible by the (traditional) mediastinoscope.[153,235,243,246-248] The FN rate at mediastinoscopy is probably also affected by the diligence with which nodes are dissected and sampled at mediastinoscopy. Ideally, five nodal stations (stations 2R, 4R, 7, 4L, and 2L) should be examined routinely,

FIGURE 9. [Sections 4.3.1.1] Accuracy of mediastinoscopy in patients with lung cancer.

First Author	Year	No.	Stage	Thoro	Prev	Sens	Spec[a]	PPV[a]	NPV
TM									
Hammoud[235]	1999	1,369	cN0-3	Sel	36	85	(100)[a]	(100)[a]	92
Lemaire[230]	2006	1,362	cN0-3	Sys	29	86	(100)[a]	(100)[a]	95
Coughlin[243]	1985	1,259	cN0-3	Sel	29	92	(100)[a]	(100)[a]	97
Luke[242, b]	1986	1,000	cN0-2	Sel	39	85	(100)[a]	(100)[a]	91
De Leyn[238]	1996	500	cN0-2	Sys	39	76	(100)[a]	(100)[a]	87
Anraku[227]	2010	352	cN0-3	Sys	37	92	(100)[a]	(100)[a]	96
Page[241, b]	1987	345	cN0-2	Sel	48	73	(100)[a]	(100)[a]	80
Dillemans[239]	1994	331	cN0-3	Sys	41	72	(100)[a]	(100)[a]	84
Brion[244]	1985	153	cN0-2	Sel	35	67	(100)[a]	(100)[a]	85
Fibla[231]	2006	142	cN0-3	Sel	42	67	(100)[a]	(100)[a]	80
Jolly[160]	1991	136	cN0-2	Sel	54	92	(100)[a]	(100)[a]	91
Ratto[125]	1990	123	cN0-2	Sel	33	88	(100)[a]	(100)[a]	94
Ebner[236, b]	1999	116	cN0-2	Sys	50	81	(100)[a]	(100)[a]	82
Annema[228]	2010	110	cN0-3	Sel	46	80	(100)[a]	(100)[a]	86
Gdeedo[153]	1997	100	cN0-3	Sys	32	78	(100)[a]	(100)[a]	91
Riordain[240]	1991	74	cN0-2	Sel	50	81	(100)[a]	(100)[a]	84
Aaby[156]	1995	57	cN0-3	Sys	44	84	(100)[a]	(100)[a]	89
Block[226]	2010	54	cN0-3	Sel	44	88	(100)[a]	(100)[a]	91
Kim[224]	2011	750	cN0	Sys	15	44	(100)[a]	(100)[a]	91
Choi[233]	2003	291	cN0	Sys	15	44	(100)[a]	(100)[a]	91
Meyers[229]	2006	169	cN0	Sel	8	38	(100)[a]	(100)[a]	95
Cerfolio[232]	2006	153	cN0-1	Sys	14	32	(100)[a]	(100)[a]	90
Deneffe[245]	1983	124	cN0	Sel	31	68	(100)[a]	(100)[a]	88
Park[225]	2010	78	cN0	Sys	8	50	(100)[a]	(100)[a]	96
Gurses[234]	2002	67	cN0	Sys	15	40	(100)[a]	(100)[a]	93
Leschber[222]	2008	52	cN0	Sys	19	…	(100)[a]	…	81
Median: cN0-3			***cN0-3***	*39% sys*	**40**	**83**			**90**
Median: cN0			***cN0***	*75% sys*	**16**	**47**			**91**
Median: sys			*46% cN0*	***sys***	27	**74**			**91**
Median: sel			*17% cN0*	***sel***	39	**81**			**91**
Summary TM: median		**9267**			**33**	**78**	**(100)[a]**	**(100)[a]**	**91**
VAM									
Venissac[223]	2003	154	cN2-3	Sys	71	97	(100)[a]	(100)[a]	94
Kimura[250]	2007	209	cN0-3	Sel	31	78	(100)[a]	(100)[a]	91
Lardinois[246]	2003	195	cN0-3	Sys	34	87	(100)[a]	(100)[a]	92
Kimura[135]	2003	125	cN0-3	Sys	36	85	(100)[a]	(100)[a]	92
Sayar[249]	2011	104	cN0-2	Sel	29	90	(100)[a]	(100)[a]	96
Anraku[227]	2010	89	cN0-3	Sys	22	95	(100)[a]	(100)[a]	99
Leschber[222]	2008	119	cN0	Sys	17	…	(100)[a]	…	83
Summary VAM: median		**995**			**31**	**89**	**(100)[a]**	**(100)[a]**	**92**
LA									
Zielinski[364]	2007	256	cN0-2	Compl	31	94	(100)[a]	(100)[a]	97
Witte[365]	2006	130	cN0-2	Compl	…	94	(100)[a]	(100)[a]	99
Summary LA: median		**386**		**compl**	**31**	**94**	**(100)[a]**	**(100)[a]**	**98**
Summary ALL: median		**10,648**			**34**	**81**	**(100)[a]**	**(100)[a]**	**91**

Inclusion criteria: studies of mediastinoscopy for lung cancer staging, involving ≥50 patients from 1980 to 2011 reporting test characteristics. Compl = complete; LA = mediastinal lymphadenectomy (via cervical mediastinoscopy approach); Sel, selective assessment; Sys = systematic assessment; Thoro = level of thoroughness of the procedure (complete, systematic, selective, limited or visual assessment of mediastinal node stations[354]; TM = traditional mediastinoscopy; VAM = video-assisted mediastinoscopy.

[a]Technically, the specificity and PPV cannot be assessed in those studies reporting 100% values because a positive result was not followed up with an additional gold standard test.

with at least one node sampled from each station unless none are present after dissection in the region of a particular node station. It has been suggested that videomediastinoscopy provides a higher yield than conventional mediastinoscopy. In pooling the data from 995 cases for this iteration of the guidelines, the sensitivity of videomediastinoscopy was higher at 89% than that of traditional mediastinoscopy (Fig 9).[135,222,223,227,246,249,250] The specificity and the FP rates of mediastinoscopy are reported to be 100% and 0%, respectively. Strictly speaking, these values cannot really be assessed because patients with a positive biopsy result were not subjected to any further procedures (such as thoracotomy) to confirm the results. Nevertheless, it seems reasonable to assume that FP results are rare. The patients included in these series had had potentially operable, nonmetastatic lung cancer with very few exceptions. The majority of these patients were in the radiographic groups B, C, and D.

Further assessment of the results of mediastinoscopy demonstrated that the newer techniques (mediastinal lymphadenectomy and videomediastinoscopy) have better results than traditional mediastinoscopy (median sensitivity of 94%, 89%, and 78% and median FN rates of 2%, 8,% and 9%, respectively). The performance of traditional mediastinoscopy is affected by the type of patients (sensitivity of 47% vs 83% for cN0 vs cN0-3), although there is little difference in the FN rates. Whether a systematic or selective level of thoroughness (level B or C) was used via traditional mediastinoscopy had little impact (as well as can be judged from the available reports). However, this may be reflective of the type of patients: systematic sampling was more common for patients with cN0 disease and selective sampling for patients with stage cN0-3 disease. It may be that using a more thorough technique is particularly important in patients without clinical suspicion of node involvement. The impact of the level of thoroughness of the procedure or the clinical node status when using the newer techniques cannot be assessed. Thus, it appears that the better visualization afforded by videomediastinoscopy should be considered to be an important feature associated with better results, whereas the importance of the thoroughness of sampling (levels A-C) is less clear. However, limited or no sampling (level D) cannot be considered acceptable.

4.3.1.2 Assessment of APW Nodes—Cancers in the left upper lobe (LUL) have a predilection for involvement of the nodes in the APW (station 5). These nodes are classified as mediastinal nodes and represent the most important group of N2 nodes not accessible by standard cervical mediastinoscopy. It has been suggested that nodes in this region not be viewed as mediastinal nodes and that resection of patients be performed regardless of APW node involvement, making assessment of these nodes superfluous.[257] This was based on a selected subgroup of 23 completely resected patients who had APW node involvement as the only site of N2 disease. However, analysis of all the data in this regard show that the survival of patients with only APW node involvement is not different from that of patients with involvement of only a single N2 node station in another location.[252] Therefore, the issue is more a matter of whether patients with involvement of a single mediastinal node station should undergo surgical resection, and not whether APW nodes should be classified as N2 nodes.

The classic method to invasively assess this area is a Chamberlain procedure (also known as an anterior mediastinotomy), which involves an incision in the second or third intercostal space just to the left of the sternum. This procedure traditionally required an overnight hospital stay, but in many institutions this is no longer necessary, especially because surgeons have used visualization between the ribs more frequently as opposed to removal of a costal cartilage. The accuracy of this procedure has not been documented extensively, despite its common use. The median sensitivity of a Chamberlain procedure for the detection of the involvement of station 5,6 nodes in patients with LUL tumors was approximately 71% among 238 patients (Fig 10).[241,245,253,254] The median NPV was 91%.

Extended cervical mediastinoscopy offers an alternative method to invasively assess APW nodes but is used in only a few institutions (Fig 10).[255-258] With this procedure, a mediastinoscope is inserted through the suprasternal notch and directed lateral to the aortic arch.[256] In 456 patients with LUL cancers, standard mediastinoscopy accompanied by extended mediastinoscopy was found to have a median sensitivity of 71% for identifying station 5,6 node involvement.[255-258] The median NPV was 91%.

Video-assisted thoracic surgery (VATS) has been used to assess APW lymph nodes. The general results of this technique are reported in Figure 11. Specific results for stations 5 and 6 have not been reported but are likely to be better because these node stations are much easier to access than any of the other mediastinal node stations.

The patients included in these series of Chamberlain procedures, extended cervical mediastinoscopy, and VATS had potentially operable lung cancer with very few exceptions. These patients were primarily from radiographic group B, with probably a few from group C. The reported results provide data regarding the reliability of these tests for the staging of mediastinal nodes as compared with thoracotomy in patients with lung cancer.

FIGURE 10. [Sections 4.3.1.2] Test parameters for assessment of paraaortic and aortopulmonary window nodes (stations 5 and 6).

First Author	Year	N	Setting	Stage	Prev	Sens	Spec[a]	PPV[a]	NPV
Anterior mediastinotomy									
Nechala[254]	2006	117	Med -	cN0,1	8	56	(100)[a]	(100)[a]	96
Barendregt[253]	1995	37	-	cN0-2	14	20	(100)[a]	(100)[a]	89
Page[241]	1987	45	CXR/TG	cN1,2	47	86	(100)[a]	(100)[a]	89
Deneffe[245]	1983	39	CXR/TG	cN0,1	38	87	(100)[a]	(100)[a]	92
Summary: median		**238**			**26**	**71**	**(100)[a]**	**(100)[a]**	**91**
Extended cervical mediastinoscopy									
Freixinet Gilart[255]	2000	93	Med -	cN2	34	81	(100)[a]	(100)[a]	91
Obiols[258]	2012	132	Med -	cN1,2[b]	19	76	(100)[a]	(100)[a]	95
Metin[257]	2011	42	Med -	cN1,2[b]	19	50	(100)[a]	(100)[a]	89
Obiols[258]	2012	89	Med -	cN0-2	10	44	(100)[a]	(100)[a]	94
Ginsberg[256]	1987	100	CXR/TG	cN0-2	29	71	(100)[a]	(100)[a]	89
Summary: median		**456**			**19**	**71**	**(100)[a]**	**(100)[a]**	**91**
Summary ALL: median		**694**			**19**	**71**	**(100)[a]**	**(100)[a]**	**91**

Inclusion criteria: studies of staging techniques for aortopulmonary window nodes, involving > 20 patients with NSCLC from 1980 to 2011 reporting test characteristics. Results are for the detection of N2 node involvement in stations 5,6 by the procedure used compared with thoracotomy. CXR/TG = chest radiograph ± tomogram (not CT scan); Med − = standard cervical mediastinoscopy negative. See Figure 6 for expansion of other abbreviations.

[a]Technically, the specificity and PPV cannot be assessed in those studies reporting 100% values because a positive result was not followed up with an additional gold standard test.

[b]Also included patients with central/hilar left upper lobe tumors.

4.3.1.3 Video-Assisted Thoracic Surgery—Thoracoscopy, also known as VATS, can be used to access mediastinal nodes. This is performed under general anesthesia and, in general, is limited to an assessment of only one side of the mediastinum. Access to the R-sided nodes is straightforward, but access to the L paratracheal nodes is more difficult. No mortality has been reported from VATS for mediastinal staging, and complications were noted in only 12 of 669 patients (average, 2%; range, 0%-9%).[137,260-266]

The performance characteristics of VATS mediastinal node biopsy for N2 node staging are shown in Figure 11.[137,259-261] The sensitivity varies widely for reasons that are not entirely clear. Even when the studies were restricted to patients with enlarged nodes, the sensitivity still ranged from 50% to 100%. The low sensitivity comes primarily from a study by Sebastián-Quetglás et al.[261] This prospective, multi-institutional study may be more generally applicable than the results from single institutions with a focused interest and extensive experience. The performance characteristics recorded here are those that apply specifically to the determination of mediastinal node status. The FN rate was about 4% in both enlarged and normal-sized nodes. In all reports, the specificity was reported as 100% and the FP rate as 0%, but this is technically not evaluable because no further testing was carried out in the event of a positive VATS result. In the 246 patients reported, the median sensitivity was 99% with a prevalence of cancer of 63%.

VATS can also be useful for further evaluation of the T stage as determined radiographically, which is useful primarily in detecting or ruling out T4 lesions

FIGURE 11. [Sections 4.3.1.3] Surgical staging of the mediastinum with video-assisted thoracic surgery.

First Author	Year	No.	Stage	Prev	Sens	Spec[a]	PPV[a]	NPV
Cerfolio[259]	2007	39	cN2	92	100	(100)[a]	(100)[a]	(100)[b]
Eggeling[137]	2002	73	cN2-3	70	98	(100)[a]	(100)[a]	96
Massone[260]	2003	55	cN2	55	100	(100)[a]	(100)[a]	100
Sebastian-Quetglas[261]	2003	79	cN0-2	24	58	(100)[a]	(100)[a]	88
Summary: median		**246**		**63**	**99**	**(100)[a]**	**(100)[a]**	**96**

Inclusion criteria: studies of video-assisted thoracopic surgery for staging of the mediastinal nodes, involving > 20 patients from 1980 to 2011 reporting test characteristics. See Figure 6 for expansion of abbreviations.

[a]Technically, the specificity and PPV cannot be assessed in those studies reporting 100% values because a positive result was not followed up with an additional gold standard test.

[b]Because NPV is increasingly affected by prevalence, and prevalence was > 80%, these values are excluded from the summary.

that preclude resection. Radiographically suspected T4 involvement was shown to be absent by VATS in 38% (29%-50%) of patients in three studies.[137,261,262] Furthermore, in 40% of patients with cytologically negative pleural effusions, the effusions were shown not to be due to malignant involvement by VATS.[262] On the other hand, routine VATS found unsuspected pleural studding in 4% (0%-5%) of patients in several studies.[137,260,261,264-267] An unsuspected malignant pleural effusion was also found in 6% in one study.[265] Most of the patients in these studies of pleural involvement had CT scan evidence of discrete node enlargement.

4.3.2 Needle Techniques:

4.3.2.1 Transthoracic NA—Transthoracic NA (TTNA) or biopsy for diagnosis of the mediastinum is distinct from TTNA of parenchymal masses to achieve a diagnosis. The ability to carry out TTNA for diagnosis and staging of the mediastinum has generally been reported to be high (about 90%), although approximately 10% of patients require placement of a catheter for evacuation of a pneumothorax.[252] The sensitivity has usually been reported to be 94%, and no studies have been added since the previous iteration of this guideline (Fig 12).[3,266-272] Patients selected for this procedure have most often had quite extensive mediastinal involvement (radiographic group A, with some group B). The mediastinal lymph nodes have generally been at least 1.5 cm, which is also likely related to the fact that the prevalence of cancer in the mediastinal nodes was very high (> 80%). Furthermore, only about 75% of the patients had lung cancer (despite excluding studies in which only a minority of patients had lung cancer). Therefore, these results are most applicable to patients with mediastinal infiltration or bulky mediastinal involvement, in whom the purpose of the procedure was probably primarily to confirm the diagnosis and less likely to confirm the stage. Extrapolation of these results to patients with lesser amounts of mediastinal spread for staging purposes may be inappropriate. Furthermore, the practical aspects of TTNA make this test unsuited for biopsy of multiple mediastinal nodes such as would be needed in patients in radiographic groups C, D, and even B. The thoroughness of assessment in the reported studies has been limited to obtaining a biopsy specimen from one site only.

4.3.2.2 Transbronchial NA—Transbronchial NA (TBNA), also known as a Wang NA, can be performed safely with no significant morbidity and on an outpatient basis, as with most bronchoscopic procedures. "Blind" or unguided TBNA is used most frequently to assess subcarinal nodes. Biopsies may also be performed with TBNA on paratracheal lymph nodes, but these are sometimes more difficult to access because of the difficulty of sufficiently angulating the bronchoscope and the needle. It is reported that it is feasible to get adequate specimens via TBNA in approximately 80% to 90% of cases.[273-276]

For this iteration of the guideline, 2,408 patients were included in an updated systematic review (Fig 13).[176,273-298] The overall median sensitivity was 78%, with values ranging from 14% to 100%. The reported specificity and FP rates were 100% and 0%, respectively, although a few studies confirmed positive TBNA results with further invasive procedures. Occasional FP results have been reported in series in which this has been specifically examined with a confirmatory test (average, 7%).[285,289,299] The median NPV, excluding studies with a prevalence > 80%, was 77%.

Patients included in studies of TBNA have generally had a very high prevalence of N2,3 involvement (average, 81%), and the general implication is that the mediastinal nodes have been markedly enlarged, although specifics about node size are generally

FIGURE 12. [Section 4.3.2.1] Transthoracic needle aspiration (percutaneous) of the mediastinum in patients with lung cancer.

First Author	Year	No.	Stage	Guidance	Prev	Sens	Spec[a]	PPV[a]	NPV
Moinuddin[271]	1984	40	cN2,3[b]	CT scan	78	100	(100)[a]	(100)[a]	100
Protopapas[268]	1996	32	cN2,3	CT scan	91	100	(100)[a]	(100)[a]	(100)[c]
Böcking[269]	1995	23	cN2,3	CT scan	65	80	(100)[a]	(100)[a]	100
de Gregorio[270]	1991	48	cN2,3[b]	Fluoro	90	72	(100)[a]	(100)[a]	(42)[c]
Westcott[272]	1981	72	cN2,3[b]	Tomo	…	94	…[d]	…[d]	…[d]
Summary: median		**215**			**84**	**94**	**(100)[a]**	**(100)[a]**	…

Inclusion criteria: studies reporting test characteristics of TTNA of mediastinal nodes/tissue in patients with lung cancer, involving > 20 patients from 1980 to 2011. Fluoro = fluoroscopy; Tomo = tomography; TTNA = transthoracic needle aspiration. See Figure 6 for expansion of other abbreviations.

[a]Technically, the specificity PPV cannot be assessed in these studies because a positive result was not followed up with an additional gold standard test.

[b]Bulky masses, corresponding to radiographic group A.

[c]Because NPV is increasingly affected by prevalence as prevalence is > 80% these values are excluded from summary calculations.

[d]Not defined because all subjects had mediastinal disease.

FIGURE 13. [Section 4.3.2.2] Transbronchial needle aspiration of the mediastinum in patients with lung cancer.

Study	Year	No.	Stage	Prev	Sens	Spec[a]	PPV[a]	NPV
Fernandez-Villar[277]	2010	280	cN1-3	…	68	(100)[a]	(100)[a]	10
Utz[294]	1993	61	cN0/N2	100	56	(100)[a]	(100)[a]	…
Selcuk[291]	2003	26	cN2-3	100	100	(100)[a]	(100)[a]	…
Wilsher[298]	1996	24	cN2-3	96	90	(100)[a]	(100)[a]	…
Katis[279]	1998	76	cN2-3	95	74	(100)[a]	(100)[a]	(20)[b]
Bilaceroglu[273]	1998	134	cN1-3	88	75	(100)[a]	(100)[a]	(36)[b]
Melloni[282]	2009	51	cN2-3	88	76	(100)[a]	(100)[a]	(33)[b]
Shannon[293]	1996	24	cN2-3	88	90	(100)[a]	(100)[a]	(60)[b]
Stratakos[294]	2008	77	cN1-3	86	88	(100)[a]	(100)[a]	(58)[b]
Schenk[288]	1993	64	cN2-3	86	56	(100)[a]	(100)[a]	(82)[b]
Wang[297]	1983	39	cN2-3	86	76	(100)[a]	(100)[a]	(71)[b]
Schenk[290]	1989	29	cN2-3	86	80	(100)[a]	(100)[a]	(44)[b]
Medford[281]	2010	79	cN2-3	84	79	(100)[a]	(100)[a]	(58)[b]
Mak[280]	2004	24	cN1-3	83	60	(100)[a]	(100)[a]	(33)[b]
Vansteenkiste[276]	1994	80	cN2	79	79	(100)[a]	(100)[a]	55
Rodriguez de castro[286]	1997	80	cN2-3	78	66	(100)[a]	(100)[a]	45
Harrow[278]	2000	264	cN1-3	72	93	99	99	80
Shah[292]	2006	129	cN1-3	71	68	(100)[a]	(100)[a]	56
Rodriguez de castro[275]	1995	56	cN2-3	70	77	(100)[a]	(100)[a]	70
Patelli[283]	2002	182	cN2	67	98	(100)[a]	(100)[a]	83
Rong[287]	1998	49	cN1-3	66	100	(100)[a]	(100)[a]	100
Rakha[284]	2010	182	cN1-3	57	84	(100)[a]	(100)[a]	70
Garpestad[274]	2001	32	cN1-3	57	83	(100)[a]	(100)[a]	67
Schenk[289]	1986	88	cN2-3	39	50	96	89	75
Bernasconi[176]	2006	113	cN2-3	31	54	(100)[a]	(100)[a]	91
Wallace[296]	2008	138	cN2-3	30	36	(100)[a]	(100)[a]	78
Ratto[285]	1988	47	cN2	30	14	(100)[a]	(100)[a]	73
Summary: median		**2,408**		**81**	**78**	**(100)[a]**	**(100)[a]**	**77**

Inclusion criteria: studies reporting test characteristics of TBNA of mediastinal nodes/tissue in patients with lung cancer, involving ≥ 20 patients from 1980 to 2011. TBNA = transbronchial needle aspiration. See Figure 6 for expansion of other abbreviations.

[a]Technically, the specificity and PPV cannot be assessed in the studies reporting 100% values because a positive result was not followed up with an additional gold standard test.

[b]Because NPV is increasingly affected by prevalence and prevalence was > 80% these values are excluded from summary calculations.

vague. The results should not be applied to patients without extensive mediastinal involvement.[300] Furthermore, the high FN rate makes this test less useful for staging of the mediastinum in patients with normal-sized nodes. Positive TBNA results demonstrate mediastinal node involvement fairly reliably. Negative TBNA results, however, cannot sufficiently exclude mediastinal nodal involvement, and additional staging procedures should be performed. When compared directly with other needle technologies, TBNA has a much lower sensitivity than the ultrasound-guided technologies, either alone or in combination (see later discussion).[296] Where available, ultrasound-guided needle techniques such as EBUS-NA or EUS-NA have largely replaced TBNA for staging of the mediastinum in patients with lung cancer.

4.3.2.3 Endoscopic Ultrasound With NA—EUS-NA of mediastinal lymph nodes through the wall of the esophagus has been performed with a negligible risk of infection or bleeding. Complications are rare[143,301-305] and no mortality has been reported. This technique is particularly useful for the inferior pulmonary ligament and the esophageal, subcarinal, and APW nodes (stations 9, 8, 7, 4L, 5). Nodes that are anterolateral to the trachea (stations 2R, 2L, 4R) are difficult to sample reliably (but are commonly involved in lung cancer). This procedure requires a skilled endoscopist with specific experience and the necessary equipment.

Overall, 2,433 patients with evaluable lung cancer were included in this analysis (Fig 14).[143,179,296,301,305-325] For the detection of malignant mediastinal (N2 or N3) lymph nodes, the median sensitivity and specificity were 89% and 100%, respectively. The median NPV was 86%.

The patients included in these studies were patients with NSCLC without evidence of distant metastases. Most of the patients had enlarged lymph nodes, which is further corroborated by an overall prevalence of

FIGURE 14. [Section 4.3.2.3] Endoscopic ultrasound-guided needle aspiration of the mediastinum in patients with lung cancer.

First Author	Year	No.	Stage	Thoro	Prev	Sens	Spec	PPV	NPV
Nadarajan[310]	2010	34	cN2-3	Sel	88	100	(100)[a]	(100)[a]	(100)[b]
Tournoy[312]	2008	100	cN0-3	Sys	83	95	(100)[a]	(100)[a]	(81)[b]
Wallace[143]	2001	121	cN2-3	Sel	79	87	(100)[a]	(100)[a]	68
Annema[323]	2004	36	cN2-3	Sys	78	93	(100)[a]	(100)[a]	80
Wiersema[305]	2001	29	cN2-3	Sel	76	100	(100)[a]	(100)[a]	100
Fritscher-Ravens[301]	2000	35	cN2-3	Lim	74	96	(100)[a]	(100)[a]	90
Annema[316]	2005	215	cN0-3	Sys	71	91	(100)[a]	(100)[a]	74
Larsen[324]	2002	29	cN2-3	Lim	69	90	(100)[a]	(100)[a]	82
Annema[306]	2010	551	cN2-3	Sys	66	83	(100)[a]	(100)[a]	75
Caddy[320]	2005	36	cN0-3	Sel	65	92	(100)[a]	(100)[a]	83
Kalade[311]	2008	33	cN1-3	Sel	64	95	(100)[a]	(100)[a]	92
Silvestri[304]	1996	26	cN0-3	Sys	62	89	(100)[a]	(100)[a]	82
Gress[302]	1998	24	cN2-3	Sel	58	93	(100)[a]	(100)[a]	90
Herth[307]	2010	139	cN1-3	Sel	52	89	(100)[a]	(100)[a]	82
Talebian[309]	2010	152	cN2-3	Sys	49	74	(100)[a]	(100)[a]	73
Sawhney[313]	2006	65	cN2-3	Sys	48	87	(100)[a]	(100)[a]	90
Fritscher-Ravens[179]	2003	33	cN0-3	Sys	48	88	(100)[a]	(100)[a]	89
Larsen[324]	2005	58	cN0-3	Sys	47	87	(100)[a]	(100)[a]	87
Eloubeidi[315]	2005	104	cN2-3	Sys	41	93	(100)[a]	(100)[a]	96
Eloubeidi[318]	2005	35	cN2-3	Sys	37	91	(100)[a]	(100)[a]	97
Annema[317]	2005	100	cN2-3	Sys	36	71	90	86	85
Wallace[322]	2004	69	cN0	Sys	36	61	(100)[a]	(100)[a]	82
LeBlanc[321]	2005	67	cN0	Sel	33	45	(100)[a]	(100)[a]	79
Wallace[296]	2008	138	cN2-3	Sys	30	69	(100)[a]	(100)[a]	88
Szlubowski[308]	2010	120	cN0	Sel	22	50	99	93	87
Fernandez-Esparrach[314]	2006	47	cN0	Sys	21	50	(100)[a]	(100)[a]	88
Median: prevalence > 80		% sys	50%			**96**			**90**
Median: prevalence 60-79		% sys	40%			**92**			**82**
Median: prevalence 40-59		% sys	71%			**88**			**88**
Median: prevalence 20-39		% sys	71%			**61**			**87**
Median: cN1-3		% sys	47%			**92**			**89**
Median: cN0-1		% sys	50%			**50**			**85**
Summary: median		**2,443**			**58**	**89**	**(100)[a]**	**(100)[a]**	**86**

Inclusion criteria: studies reporting test characteristics of EUS-NA for staging of lung cancer, involving ≥ 20 patients from 1980 to 2011. EUS-NA = endoscopic ultrasound and needle aspiration; Lim = limited. See Figures 6 and 9 for expansion of other abbreviations.

[a]Technically, the specificity and PPV cannot be assessed in those studies reporting 100% values because a positive result was not followed up with an additional gold standard test.

[b]Because NPV is increasingly affected by prevalence and prevalence was > 80% these values are excluded from summary calculations.

disease of about 60%. Furthermore, it must be remembered that patients undergoing EUS were generally selected because they had suspected nodal involvement in locations amenable to EUS-NA. Thus, the population undergoing EUS has been primarily in radiographic group B, with only some in C and probably fewer in A. However, it is clear that nodes that are < 1 cm can be sampled using this technique.[301,325]

EUS-NA is also capable of detecting metastatic disease to subdiaphragmatic sites such as the left adrenal gland, celiac lymph nodes, and the liver. The overall yield was 4% (37 of 834 patients) for such M1 disease detected by EUS-NA.[301,305,315-317,319,321,322] Actual performance characteristics for the detection of M1 disease by EUS-NA cannot be calculated because patients generally do not undergo exploration of the abdomen.

EUS is also capable of evaluating the presence of direct tumor invasion into the mediastinum (T4). Several groups[301,315-317,319,321,325,326] have evaluated the prevalence of T4 disease, but only one[326] has specifically evaluated the reliability of EUS for T staging. The FP rate in that study was 30%, making this technique unreliable for assessing mediastinal invasion.

The cost of EUS is lower than that of surgical staging procedures, probably because of the ability to perform EUS without general anesthesia in an ambulatory setting. Two studies have suggested that EUS may be more cost effective than mediastinoscopy, although these studies assumed that mediastinoscopy frequently required inpatient admission.[326,327]

4.3.2.4 Endobronchial Ultrasound With NA—Since the last iteration of this guideline, endobronchial ultrasound with NA has been used increasingly to stage lung cancer, as evidenced by the marked

increase in publications on the subject. This has been accompanied by a better understanding of the indications and performance characteristics of this procedure. Overall, 2,756 patients met the inclusion criteria for mediastinal staging with EBUS-NA (Fig 15).[210,296,307,308,329-350] The overall median sensitivity was 89%, with values ranging from 46% to 97%. The median NPV was 91%.

For the most part, studies using EBUS have involved patients with discrete lymph node enlargement (radiographic group B and some group A and C), consistent with a disease prevalence of approximately 58%. Initial studies focused on patients with fairly sizable lymph nodes who were clinically likely nonoperable. However, some studies reporting the performance characteristics of EBUS in patients who were potentially operable have been published. Two studies focused on patients with a radiographically normal mediastinum by either CT scan or CT and PET scans and discovered unsuspected mediastinal metastases.[210,351]

Most of the studies evaluating EBUS have used a systematic approach, evaluating representative nodes from each node station. Comparing results from studies using a systematic approach with those using a more selective approach shows only small differences. However, most of the patients evaluated had suspected N2,3 disease, and the level of thoroughness (systematic vs selective) may be less important in this group. The impact of a complete assessment or a limited assessment cannot be assessed at this point because sufficient data are not available.

FIGURE 15. [Section 4.3.2.4] Real-time endobronchial ultrasound-guided transbronchial needle aspiration of the mediastinum in patients with lung cancer.

Study	Year	No.	Stage	Thoro	Prev	Sens	Spec[a]	PPV[a]	NPV
Fielding[341]	2009	68	cN1-3	Sel	87	95	(100)[a]	(100)[a]	(67)[b]
Steinfort[334]	2011	117	cN1-3	Sys	80	97	(100)[a]	(100)[a]	87
Cetinkaya[332]	2011	52	cN2-3	Sys	80	95	(100)[a]	(100)[a]	83
Rintoul[344]	2009	109	cN1-3	Sys	77	91	(100)[a]	(100)[a]	60
Gilbert[339]	2009	67	cN1-3	Sel	70	93	(100)[a]	(100)[a]	83
Yasufuku[349]	2005	108	cN1-3	Sys	69	95	(100)[a]	(100)[a]	90
Yasafuku[350]	2004	70	cN1-3	Sys	67	96	(100)[a]	(100)[a]	92
Szlubowski[343]	2009	226	cN0-3	Sys	64	89	(100)[a]	(100)[a]	84
Ye[333]	2011	101	cN1-3	Sel	63	95	(100)[a]	(100)[a]	93
Cerfolio[336]	2010	92	cN2	Sys	63	57	(100)[a]	(100)[a]	79
Lee BE[329]	2012	73	cN0-3	Sys	62	95	(100)[a]	(100)[a]	94
Bauwens[345]	2008	106	cN1-3	Sys	58	95	(100)[a]	(100)[a]	91
Sun[337]	2010	49	cN1-3	Sys	53	85	96	96	85
Herth[307]	2010	139	cN1-3	Sel	52	91	(100)[a]	(100)[a]	92
Memoli[331]	2011	100	cN1-3	Sys	47	87	(100)[a]	(100)[a]	89
Omark Petersen[340]	2009	151	cN2-3	Lim	43	85	(100)[a]	(100)[a]	89
Yasufuku[330]	2011	153	cN0-3	Sys	35	81	(100)[a]	(100)[a]	91
Hwangbo[335]	2010	150	cN2-3	Sys	31	84	(100)[a]	(100)[a]	93
Wallace[296]	2008	138	cN2-3	Sys	30	69	(100)[a]	(100)[a]	88
Lee HS[346]	2008	102	cN2-3	Sys	30	94	(100)[a]	(100)[a]	97
Hwangbo[342]	2009	117	cN2-3	Sys	26	90	(100)[a]	(100)[a]	97
Yasufuku[348]	2006	102	cN1-3	Sys	25	92	(100)[a]	(100)[a]	97
Szlubowski[343]	2010	120	cN0	Sel	22	46	99	93	86
Herth[211]	2006	100	cN0	Sys	21	92	(100)[a]	(100)[a]	96
Nakajima[338]	2010	49	cN1-3	Sys	18	67	(100)[a]	(100)[a,c]	93
Herth[210]	2008	97	cN0	Sys	10	89	(100)[a]	(100)[a,c]	99
Median: Prevalence ≥ 80						**96**			**83**
Median: Prevalence 60-79						**91**			**83**
Median: Prevalence 40-59						**87**			**89**
Median: Prevalence 20-39						**87**			**95**
Median: Prevalence < 20						**78**			**96**
Median: cN1-3						**91**			**89**
Median: cN0						**89**			**96**
Summary: median		**2,756**			**58**	**89**	**(100)[a]**	**(100)[a]**	**91**

Inclusion criteria: studies reporting test characteristics of EBUS-TBNA for staging of lung cancer, involving ≥ 20 patients from 1980 to 2011. EBUS-TBNA = endobronchial ultrasound and transbronchial needle aspiration. See Figures 6 and 9 for expansion of other abbreviations.

[a]Technically, the specificity and PPV cannot be assessed in those studies reporting 100% values because a positive result was not followed up with an additional gold standard test.

[b]Because NPV is increasingly affected by prevalence and prevalence was > 80% these values are excluded from summary calculations.

[c]Because PPV is increasingly affected by prevalence as prevalence is < 20% these values are excluded from summary calculations.

4.3.2.5 Combined EUS/EBUS—Emerging data suggest that the combination of EUS-NA and EBUS-NA may allow complementary and near-complete access to all mediastinal lymph node stations. Seven studies with 811 patients used this combined approach and met the inclusion criteria for this analysis. The pooled median sensitivity and specificity were 91% and 100%, respectively, with a prevalence of cancer of 33% in this population (Fig 16).[228,296,307,308,335,352,353] The median NPV was 96%. The ability to perform both procedures in a single session is appealing, although there are many unresolved issues regarding training and the availability of combined endoscopic and bronchoscopic expertise.

4.3.2.6 Comparative Effectiveness Trials—Most of the published literature for staging of the mediastinum in patients with lung cancer has been single-institution studies that compare one technology for staging lung cancer (eg, EBUS) with the historic gold standard (ie, surgical lymphadenectomy) to assess the performance characteristics of the technology in question. What has been lacking is a direct comparison of staging technologies in similar patients to help inform physicians about which technology may be most useful in a given clinical situation. Two studies provide insight into how these techniques compare with one another. Wallace et al[296] compared TBNA, EBUS-NA, EUS-NA, and combined EBUS/EUS NA in the same patient. The procedures were performed consecutively, and pathologists were blinded to the source of the specimen. The sensitivities were 93%, 69%, 69%, and 35% for the combined procedure (EBUS/EUS), EBUS alone, EUS alone, and TBNA, respectively. Even among bronchoscopy-favorable locations such as the subcarinal nodes, TBNA performed poorly (sensitivity, 47%) in comparison with the ultrasound-guided approaches.

A multicenter RCT of 241 patients compared surgical staging alone with combined EBUS/EUS (endosonography) followed by surgical staging if the needle approach was negative.[228] The sensitivities of surgery, endosonography, and endosonography followed by surgery if the needle technique was negative were 79%, 85% and 94%, respectively. Parenthetically, the sensitivities of each technique individually are nearly identical to the pooled estimates published in this guideline. This study involved a systematic level of thoroughness for both the endosonography and mediastinoscopy and complete dissection (level A) for intraoperative staging. The rate of noncurative resection was 18% in the mediastinoscopy arm compared with 7% in the endosonography arm ($P < .02$). The complication rate was similar in both groups (6% vs 7%); however, 12 of the 13 complications were in patients who underwent surgical staging. The conclusion of this study was that patients should start with endosonography and if it is negative, move to surgical staging of the mediastinum. Nearly two-thirds of the patients in this study had discrete N2,3 node enlargement, with most of the rest having central (hilar) tumors of c N1 involvement.

4.4 Approach to the Patient

In patients with lung cancer and no distant metastases, accurate assessment of the status of mediastinal nodes is critical in choosing the best treatment strategy. Many different tests and procedures are available as discussed in the previous sections, making it seem difficult to choose which approach is best.

In choosing an invasive staging test, several issues must be considered. First of all is the availability of different procedures. All invasive tests require some specialized experience and skill, and physicians who

FIGURE 16. [Section 4.3.2.5] Real-time EBUS-TBNA and EUS-NA of the mediastinum in patients with lung cancer.

First Author	Year	No.	Stage	Thoro	Prev	Sens	Spec[a]	PPV[a]	NPV
Vilmann[353]	2005	31	cN0-3	sys	65	100	(100)[a]	(100)[a]	100
Annema[228]	2010	123	cN1-3	sys	54	82	(100)[a]	(100)[a]	80
Herth[307]	2010	139	cN1-3	sel	52	96	(100)[a]	(100)[a]	96
Ohnishi[352]	2011	110	cN0-3	sys	35	72	(100)[a]	(100)[a]	87
Hwangbo[335]	2010	150	cN2-3	sys	31	91	(100)[a]	(100)[a]	96
Wallace[296]	2008	138	cN2-3	sys	30	93	(100)[a]	(100)[a]	97
Szlubowski[308]	2010	120	cN0	sel	22	68	98	91	91
Median: prevalence 40-65						**96**			**96**
Median: prevalence 20-39						**82**			**94**
Summary: median		**811**			**33**	**91**	**(100)[a]**	**(100)[a]**	**96**

Inclusion criteria: studies reporting test characteristics of combined EBUS-TBNA/EUS-NA for staging of lung cancer, involving ≥ 20 patients from 1980 to 2011. See Figures 6 and 9 for expansion of abbreviations.
[a]Technically, the specificity and PPV cannot be assessed in those studies reporting 100% values because a positive result was not followed up with an additional gold standard test.

perform these procedures infrequently may not be able to achieve the diagnostic accuracy reported by high-volume institutions. This is equally true of both the surgical staging techniques and the needle techniques. Second, the location of the suspicious nodes is important, because nodes in one location may be accessible only by a particular approach (eg, stations 5 and 6 cannot be accessed by the needle techniques, and either a VATS approach or a left anterior mediastinotomy are required to reach those areas) There may be factors related to patient comorbidity that argue against certain approaches, such as mediastinoscopy, which usually requires general anesthesia. The morbidity and mortality of invasive procedures may be a consideration, although complications appear to be infrequent. Finally, cost may be a consideration.

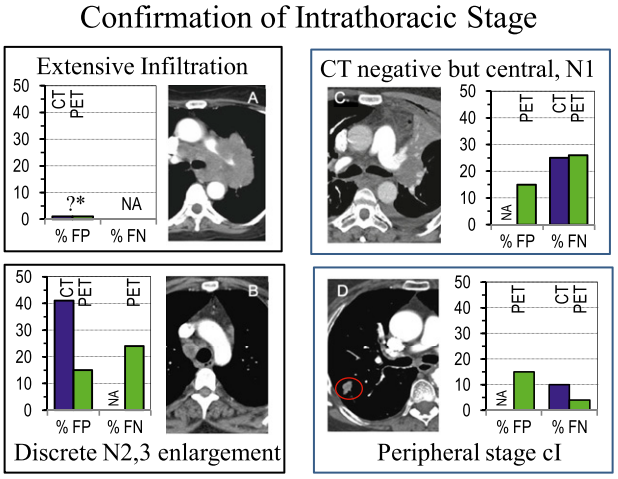
A key factor in applying the data and recommendations presented here is how a procedure to evaluate stage is performed. A classification of levels of thoroughness has been developed and provides a guide.[354] Level A involves complete sampling of each node in each major mediastinal node station (2R, 4R, 2L, 4L, 7, and possibly 5 or 6), level B involves a systematic sampling of each node station, level C involves a selective sampling of suspicious nodes only, and level D involves very limited or no sampling, with only visual assessment. Which level of thoroughness is necessary for different situations has not been well established, but it is important to recognize that much of the literature involves a level B assessment; centers performing a level C or D assessment may not experience the same results.

The sensitivity of various invasive mediastinal staging tests in patients with cN2,3 disease appears to be similar. A strict comparison is not justified, because the patients undergoing these procedures are not comparable because of differences in how they are selected for a particular procedure (eg, the location of the nodes). Furthermore, the sensitivity and the NPV may depend on the experience of those performing the procedure and on the level of thoroughness with which it is performed.

4.4.1 Mediastinal Infiltration: In patients with extensive mediastinal infiltration, the radiographic evidence of mediastinal involvement is almost universally considered adequate (Fig 17).[225,229,252,355,356] There are no data to prove this, because invasive confirmation is not carried out. However, even though staging is not an issue, tissue is needed to confirm the diagnosis and to define the histologic and molecular genetic characteristics of the tumor. In this case, it does not matter whether the tissue is obtained from the primary tumor or from a mediastinal site.

In patients in whom diagnosis is the primary issue, tissue should be obtained by whichever method is easiest. In other words, the choice of procedure will be governed primarily by patient-specific (anatomic, convenience, and comorbidity) factors, instead of the performance characteristics of a test. Although sputum cytology was adequate in the past, in an era in which molecular diagnostics are being performed more routinely to help guide treatment decisions, it is likely that more specimens will be needed to adequately perform diagnostic analysis.

FIGURE 17. [Section 4.4.1, 4.4.3, 4.4.5, 4.4.7] False-positive and false-negative rates for CT scan and PET scan assessment of mediastinal nodes by the American College of Chest Physicians intrathoracic radiographic (CT scan) classification categories. References by radiographic category: A, Estimated. B, CT scan[252] and PET scan.[25,123,164,355] C, CT scan[252] and PET scan.[24-26,123] D, CT scan[252] and PET scan.[24-26,225,229,356] % FN = % of negative test results that are false negative (100 − negative predictive value %); % FP = % of positive test results that are false positive (100 − positive predictive value %); NA = not applicable; ?* = estimated; no actual data available for A.



4.4.2 Recommendation

4.4.2.1. For patients with extensive mediastinal infiltration of tumor and no distant metastases, it is suggested that radiographic (CT) assessment of the mediastinal stage is usually sufficient without invasive confirmation (Grade 2C)**.**

4.4.3 Discrete Mediastinal Node Enlargement: Many patients present with a CT scan demonstrating enlargement of discrete mediastinal (N2,3) lymph nodes. In such patients, the risks of FP test results from either CT scanning and/or PET scanning are too high to rely on imaging alone to determine the mediastinal stage of the patient, and tissue confirmation is necessary (Fig 17).

The sensitivity of various invasive mediastinal staging tests in patients with cN2,3 disease appears to be similar. A strict comparison is not justified, because the patients undergoing these procedures are not comparable because of differences in how they are

selected for a particular procedure (eg, the location of the nodes). Needle-based mediastinal staging is the best approach; the invasive staging procedure has a high chance of being positive and the needle-based techniques have lower morbidity than surgical staging. Furthermore, the RCT of mediastinoscopy alone vs combined EBUS/EUS with surgical staging if the needle approach was negative demonstrated advantages to the needle-first approach.[228]

An option for the treatment of patients with stage IIIA NSCLC and discrete mediastinal node involvement is induction therapy followed by surgery (see Ramnath et al,[362] "Treatment of Stage III Non-small Cell Lung Cancer," in the ACCP Lung Cancer Guidelines). If this approach is chosen, the role of mediastinal restaging after induction therapy is unclear. However, some people argue that the approach should include surgery only in those patients who have a response in the mediastinum to induction therapy. It has been shown repeatedly that CT scan evidence of tumor shrinkage is notoriously misleading.[169,170] PET scanning for mediastinal restaging has also been shown to have high FP and FN rates.[169,1703] A repeat mediastinoscopy is generally safe and feasible (82% to 100% of the time), but sensitivity is limited to about 70% to 82%,[249,358-360] and most surgeons are uncomfortable with this procedure. Because a first-time mediastinoscopy is probably the best way to accomplish mediastinal restaging, an argument can be made to use a NA technique initially to document N2,3 involvement and to save mediastinoscopy for the restaging procedure after the induction therapy. All of this applies only if the adopted treatment policy is one of induction therapy, with subsequent therapy to be determined by the results of mediastinal restaging (despite the lack of data defining the role of surgery and restaging).

4.4.4 Recommendations

4.4.4.1. In patients with discrete mediastinal lymph node enlargement (and no distant metastases) with or without PET uptake in mediastinal nodes, invasive staging of the mediastinum is recommended over staging by imaging alone (Grade 1C)**.**

4.4.4.2. In patients with PET activity in a mediastinal lymph node and normal appearing nodes by CT (and no distant metastases), invasive staging of the mediastinum is recommended over staging by imaging alone (Grade 1C)**.**

4.4.4.3. In patients with high suspicion of N2,3 involvement, either by discrete mediastinal lymph node enlargement or PET uptake (and no distant metastases), a needle technique (EBUS-NA, EUS-NA or combined EBUS/EUS-NA) is recommended over surgical staging as a best first test (Grade 1B)**.**

Remark: This recommendation is based on the availability of these technologies (EBUS-NA, EUS-NA or combined EBUS/EUS-NA) and the appropriate experience and skill of the operator.

Remark: In cases where the clinical suspicion of mediastinal node involvement remains high after a negative result using a needle technique, surgical staging (eg, mediastinoscopy, VATS, etc) should be performed.

Remark: The reliability of mediastinal staging may be more dependent on the thoroughness with which the procedure is performed than by which test is used.

4.4.5 Central and Clinical N1 Nodes: Patients with no evidence of mediastinal node enlargement but with a central tumor or N1 node involvement represent another distinct group (group C). It is reasonable to consider patients with central tumors together with those with N1 node enlargement, because it is usually difficult to assess the N1 nodes in the case of a central tumor. Extensive data indicate that the FN rate of CT scanning with respect to the mediastinal nodes in these individuals is 20% to 25%.[255] More limited data demonstrate that the FN rate for PET scanning in the mediastinal nodes in this situation is similarly high (about 25%) (Fig 17).[24-26,123] Thus, invasive staging is required in these patients despite the negative CT scan and even a negative PET scan.

In general, a needle technique, with mediastinoscopy reserved for patients with a negative needle results, appears to be a good first choice, if performance of such an approach with a thorough technique is available. This is based on the results of a multicenter RCT,[231] although patients with central or cN1 involvement were not analyzed separately. How thoroughly a needle technique is performed (as well as the availability and thoroughness of mediastinoscopy) also likely has a bearing on the importance of following up on a negative needle result with mediastinoscopy.

4.4.6 Recommendations

4.4.6.1. In patients with an intermediate suspicion of N2,3 involvement, ie, a radiographically normal mediastinum (by CT and PET) and a central tumor or N1 lymph node enlargement (and no distant metastases), invasive staging of the mediastinum is recommended over staging by imaging alone (Grade 1C)**.**

4.4.6.2. In patients with an intermediate suspicion of N2,3 involvement, ie, a radiographically normal mediastinum (by CT and PET) and a central tumor or N1 lymph node enlargement (and no distant metastases), a needle technique (EBUS-NA, EUS-NA or combined EBUS/EUS-NA) is suggested over surgical staging as a best first test (Grade 2B)**.**

Remark: This recommendation is based on the availability of these technologies (EBUS-NA, EUS-NA or combined EBUS/EUS-NA) and the appropriate experience and skill of the operator.

Remark: In cases where the clinical suspicion of mediastinal node involvement remains high after a negative result using a needle technique, surgical staging (eg, mediastinoscopy, VATS, etc) should be performed.

Remark: The reliability of mediastinal staging may be more dependent on the thoroughness with which the procedure is performed than by which test is used.

4.4.7 Peripheral Stage I Tumors: For patients with peripheral tumors in whom there is no enlargement of N1-N3 nodes by CT scan, the FN rate of this radiographic assessment in the mediastinum is approximately 10%.[255] The incidence is lower in patients with T1 tumors (9%) than in those with T2 tumors (13%).[255] Whether this is viewed as high enough to justify invasive staging is a matter of judgment. A negative PET scan in the mediastinum carries an FN rate of approximately 4% (3%-6%) in this group of patients (Fig 3).[24-26,232] Thus, invasive staging is probably not needed in this patient group, especially if a PET scan is negative in the mediastinum.

4.4.8 Recommendation

4.4.8.1. For patients with a peripheral clinical stage IA tumor (negative nodal involvement by CT and PET), it is suggested that invasive preoperative evaluation of the mediastinal nodes is not required (Grade 2B)**.**

4.4.9 Patients With LUL Tumors: Patients with tumors in the LUL deserve special mention because the aortic arch raises the technical issue of access to the mediastinal nodes in the APW (station 5). This node station is the most likely mediastinal nodal area to be involved in the case of a LUL tumor, whereas it is extremely unlikely to be involved in patients with a tumor in any of the other lobes. Of course, mediastinal nodal involvement from an LUL tumor can also extend to other node stations, such as the subcarinal (station 7) or paratracheal (stations 4L, 4R, 2L and 2R) areas. A full assessment of potentially involved mediastinal node stations in the case of an LUL tumor requires investigation of the paratracheal and subcarinal nodes, as well as a separate procedure to access the APW area. The technical issues of access to the APW nodes raise questions about whether a separate invasive test for assessment of these nodes is really necessary (see section on involvement of APW nodes).

The definition of radiographic groups (A, B, C, and D) is the same no matter which lobe of the lung is involved. In addition, the indications for invasive staging of the mediastinum in patients with LUL tumors should follow the same guidelines as those for patients with a tumor in a different lobe (patients with either enlarged mediastinal nodes, a central tumor, or N1 nodal enlargement and a normal mediastinum, or with evidence of PET scan uptake in mediastinal areas, should undergo invasive mediastinal staging).

If the usual mediastinal node stations (2R, 4R, 7, 2L, and 4L) are found to be negative, whether a separate procedure to assess the station 5 area is needed is controversial. However, given the lack of clear data that involvement of only this station carries a different prognosis than involvement of a different single mediastinal node station, and with the availability of techniques to assess the APW area, the guidelines committee favors pursuing an invasive assessment of the APW nodes (using VATS, Chamberlain, or extended cervical mediastinoscopy). A finding of involvement in one mediastinal area may preclude the necessity of biopsy of other areas, especially if an additional procedure should be necessary.

Modification of these suggestions may be necessary because of the availability of expertise with the invasive procedures. However, it is suggested that referral to a center with the appropriate volume and expertise be considered if there is not expertise with at least one invasive APW staging procedure at the referring institution.

4.4.10 Recommendation

4.4.10.1. For the patients with a LUL cancer in whom invasive mediastinal staging is indicated as defined by the previous recommendations, it is suggested that invasive assessment of the APW nodes be performed (via Chamberlain, VATS, or extended cervical mediastinoscopy) if other mediastinal node stations are found to be uninvolved (Grade 2B)**.**

5.0 Summary

CT scanning of the chest is useful in providing anatomic detail that better identifies the location of

the tumor and its proximity to local structures and determines whether lymph nodes in the mediastinum are enlarged. Unfortunately, the accuracy of chest CT scans in differentiating benign from malignant lymph nodes in the mediastinum is unacceptably low. PET scanning provides functional information of tissue activity and has much better sensitivity and specificity than chest CT scanning for staging lung cancer in the mediastinum. In addition, distant metastatic disease can be detected by PET scans, and noncurative resections can be averted. Still, positive findings on PET scans can occur from nonmalignant causes (eg, infections), so tissue sampling to confirm suspected metastasis is almost always required to ensure that potential surgical candidates are not misclassified as having advanced disease. Confirmation of mediastinal nodal status can be performed using a myriad of invasive tools. Although this guideline recommends the use of minimally invasive guided needle techniques as the test of first choice, the location of the lymph node, patient comorbidities, and local availability of and expertise with the different invasive staging tools will continue to drive which tool is used in which patient. It is far more important to obtain a tissue sample of the mediastinal node or nodes in question than to quibble over which invasive staging tool was used to get there.

The clinical evaluation tool (ie, a thorough history and physical examination) remains the best predictor of distant metastatic disease. PET or PET-CT scanning is used increasingly to stage lung cancer because these tests provide important information about the tumor, the mediastinum, and distant metastatic disease, excluding in the brain. There is evidence that the use of PET scanning decreases the number of noncurative resections and may be cost effective in patients with NSCLC.

Abnormalities detected by any of the aforementioned imaging studies are not always cancer. Unless overwhelming evidence of metastatic disease is present on an imaging study, when it will make a difference in treatment, all abnormal scans require tissue confirmation of malignancy so that patients are not denied the opportunity to have potentially curative treatment.

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Dr Silvestri: contributed to the literature review with review of abstracts and construction of evidence tables, the interpretation of evidence tables and the formulation of recommendations, and the writing of the manuscript.
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Dr Jantz: contributed to the literature review with review of abstracts and construction of evidence tables, the interpretation of evidence tables and the formulation of recommendations, and the writing of the manuscript.
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Dr Harris: contributed to the interpretation of evidence tables and the formulation of recommendations and the writing of the manuscript.
Dr Detterbeck: contributed to the literature review with review of abstracts and construction of evidence tables, the interpretation of evidence tables and the formulation of recommendations, and the writing of the manuscript.
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Additional information: The supplement table can be found in the "Supplemental Materials" area of the online article.

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Endobronchial ultrasound: new insight for the diagnosis of sarcoidosis

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ABSTRACT: A diagnosis of sarcoidosis should be substantiated by pathological means in order to thoroughly exclude other diseases. The role of real-time endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) in the diagnosis of sarcoidosis has not been reported. The purpose of the present study is to evaluate the diagnostic yield of EBUS-TBNA in demonstrating the pathological features of sarcoidosis.

In total, 65 patients with suspected sarcoidosis, with enlarged hilar or mediastinal lymph nodes on computed tomography, were included in the study. Patients with a suspected or known malignancy or previously established diagnosis of sarcoidosis were excluded. Convex probe endobronchial ultrasonography integrated with a separate working channel was used for EBUS-TBNA. Surgical methods were performed in those in whom no granulomas were detected by EBUS-TBNA. Patients were followed up clinically.

EBUS-TBNA was performed on a total of 77 lymph node stations in 65 patients. A final diagnosis of sarcoidosis was made for 61 (93.8%) of the patients. The remaining four patients were diagnosed as having Wegener's granulomatosis (n=1) or indefinite (n=3). In patients with a final diagnosis of sarcoidosis, EBUS-TBNA demonstrated noncaseating epithelioid cell granulomas in 56 (91.8%) of the patients. No complications were reported.

Endobronchial ultrasound-guided transbronchial needle aspiration proved to be a safe procedure with a high yield for the diagnoses of sarcoidosis.

KEYWORDS: Bronchoscopy, hilar lymphadenopathy, mediastinum, sarcoidosis, transbronchial needle aspiration, ultrasound

Sarcoidosis is a multisystemic disorder of unknown aetiology characterised by non-caseating epithelioid cell granulomas. A minority of patients may progress to multiorgan failure. Approximately a quarter of patients with chronic sarcoidosis die due to respiratory failure. The incidence of sarcoidosis has been increasing, possibly explained by greater awareness and recognition of the condition [1]. A diagnosis of sarcoidosis can be greatly substantiated by excluding other disease possibilities, using appropriate clinicoradiological, cytological or histological tissue examination, especially when treatment with systemic steroids is contemplated. Cutaneous involvement occurs in only ~25% of patients. Erythema nodosum, the hallmark of acute sarcoidosis, is rare in the Japanese [2]. Biopsy of these lesions does not show granulomas [2]. On the contrary, up to 90% of patients show radiological evidence of thoracic hilar lymph node enlargement and present with acute or insidious respiratory symptoms [3]. Transbronchial lung biopsy (TBLB) is the recommended procedure in most cases. The diagnostic yield, however, depends largely upon the experience of the operator and number of biopsy specimens [2]. Furthermore, TBLB is a procedure that carries a risk of pneumothorax and haemoptysis [4].

Mediastinoscopy has been the method of choice when TBLB is futile [2, 5]. However, it is invasive, carried out under general anaesthesia, costly, requires in-patient care and has a complication rate of 2–3% [6]. This realisation led to the search for a less invasive tool with high diagnostic yield and minimal complications.

Convex-probe (CP) endobronchial ultrasonography (EBUS) has thus been evaluated in the present study. A preliminary study using CP-EBUS was performed on surgically resected specimens, and the feasibility of using it to perform real-time EBUS-guided transbronchial needle aspiration (TBNA) was determined prior to its clinical use [7]. EBUS-TBNA was first proven to be clinically useful in the evaluation of mediastinal and hilar lymph nodes under local anaesthesia and conscious sedation [8]. It also played a significant role in the diagnosis and

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staging of lung cancer with hilar and mediastinal lymph node involvement [9, 10]. To the present authors' knowledge, the role of EBUS-TBNA in the diagnosis of sarcoidosis has not been established. Therefore, the present study was carried out to evaluate the diagnostic yield of EBUS-TBNA in demonstrating granulomas in patients with sarcoidosis.

METHODS

Patients

The present study was conducted in both Germany (Chest Clinic, University of Heidelberg, Heidelberg) and Japan (Chiba University, Chiba), between June 2003 and October 2005. All patients with clinical and radiological features suggestive of sarcoidosis were considered if computed tomography (CT) revealed hilar or mediastinal lymph node enlargement (short axis of >1 cm). Patients with a suspected or known malignancy or previously established diagnosis of sarcoidosis were excluded. Written informed consent was obtained from all patients recruited into the study, which was approved by the respective local ethical committee. All patients were managed on an outpatient basis unless already admitted to the hospital for other reasons. Conventional flexible bronchoscopy (model BF-240 bronchovideoscope; Olympus, Tokyo, Japan) was performed first, in a standard fashion, and followed by EBUS-TBNA using the ultrasound bronchoscope (XBF-UC260F-OL8; Olympus) on the same bronchoscopy setting. Both bronchoscopic procedures were performed under local anaesthesia and conscious sedation with midazolam in both study centres. In a previous study, EBUS-TBNA of the mediastinal and hilar lymph nodes was shown to be safe and exhibit a good diagnostic yield [8]. The decision as to whether or not to proceed to TBLB, which may give rise to pneumothorax or haemorrhage, was left to the discretion of the operators. A diagnosis of sarcoidosis was made if clinico-radiological findings were supported by pathological tissue demonstrating noncaseating granulomas without necrosis and a negative culture result from EBUS-TBNA, or other surgical methods, such as mediastinoscopy or thoracotomy. Other granulomatous diseases were excluded by reviewing a patient's history and microbiological results. Cases were classified as indefinite if no diagnosis could be made. After the procedures, all patients were followed up clinically and radiologically for 18 months.

Procedure

CP-EBUS was performed with a convex transducer with a frequency of 7.5 MHz integrated at the tip of a flexible bronchoscope. The outer diameter of the insertion tube of the flexible bronchoscope was 6.7 mm, and that of the tip was 6.9 mm. The angle of view was 90°, and the direction of view was 30° forward oblique. This CP-EBUS is a linear curved-array transducer that scans parallel to the insertion direction of the bronchoscope. Images can be obtained by direct contact with the probe or by attaching an inflated balloon filled with saline to the tip, which keeps the probe in contact while sampling the lymph node. The ultrasound image was processed in a dedicated ultrasound scanner (model EU-C2000; Olympus) and visualised simultaneously with the conventional bronchoscopy image on the same monitor. This system has an integrated colour Doppler mode which permits blood vessels to be identified and inadvertent puncturing to be avoided. The inner diameter of the working channel was 2.0 mm. A dedicated 22-gauge needle was developed to perform TBNA. The inner diameter of this needle was almost equal to that of a conventional 21-gauge needle, which permits the sampling of histological cores in some cases.

Bronchoscopic procedures were performed orally. The lymph node station was identified according to the International Staging System for Lung Cancer (Mountain classification). The designated lymph node was punctured under direct EBUS guidance. The aspirated material was smeared on to glass slides. Smears were air-dried and fixed in 95% alcohol. Dried smears were evaluated by an on-site cytopathologist in order to ensure that the cell material obtained was of adequate quality. Adequate cell material was defined as sufficient for a specific diagnosis, such as the presence of noncaseating granulomas without necrosis or the presence of lymphocytes. If adequate tissue was not obtained by on-site cytology after five passes, the procedure was terminated. Furthermore, Papanicolaou staining and light microscopy was carried out by an independent cytopathologist, blinded to case details. Histological specimens were fixed in formalin before being sent to pathology. Aspirated material was also sent for microbiological examination, including special staining for fungi and acid-fast bacilli, as were specimens for culture for tuberculosis and fungi. All patients underwent chest radiography after the procedure to ensure that pneumothorax did not occur.

RESULTS

In total, 65 patients (35 males), with a mean age of 45 yrs (range 19–81), met the inclusion criteria. Both German (n=42) and Japanese (n=23) patients were included in the study population. Of this population, 74% exhibited radiological stage I disease, whereas the rest had stage II disease. Among all of the lymph nodes with a shortest diameter of ⩾1 cm on CT, 68 hilar and 134 mediastinal lymph nodes were found matching the typical description of sarcoidosis with bilateral hilar lymphadenopathy. EBUS was able to detect the enlarged lymph nodes in all of the recruited patients, and EBUS-TBNA (fig. 1) was successfully performed in all cases. In all cases, the balloon was used in order to maintain good visualisation during aspiration of the lymph nodes. Granulomas or benign lymphoid cells were detected in the aspirated materials in 62 patients. Of the 65 patients with suspected sarcoidosis, a final diagnosis of sarcoidosis was made in 61 patients (94%). A total of 77 lymph nodes were recorded and aspirated, giving a mean of 1.2 sampled lymph nodes per patient. This small number of aspirations can be explained by virtue of the rapid on-site cytopathological evaluation; once an adequate sample was obtained, the operator stopped puncturing other lymph nodes (table 1). The mean size of the enlarged lymph nodes, as measured by EBUS, was 20.5 mm (range 7–37; table 1). Of the enlarged lymph nodes, 67 (87%) were located in the mediastinal region and the remaining 10 (13%) around the hilum or interlobar area. The most commonly sampled lymph node station (29 out of 77; 38%) was subcarinal (station 7), where the mean size was 22.4 mm (range 16–31). More than half (45 out of 77; 58%) of the enlarged lymph nodes were found in the subcarinal or right lower paratracheal area, located in close proximity to the carina. The largest lymph node (37 mm) was found in the right-sided hilar area.

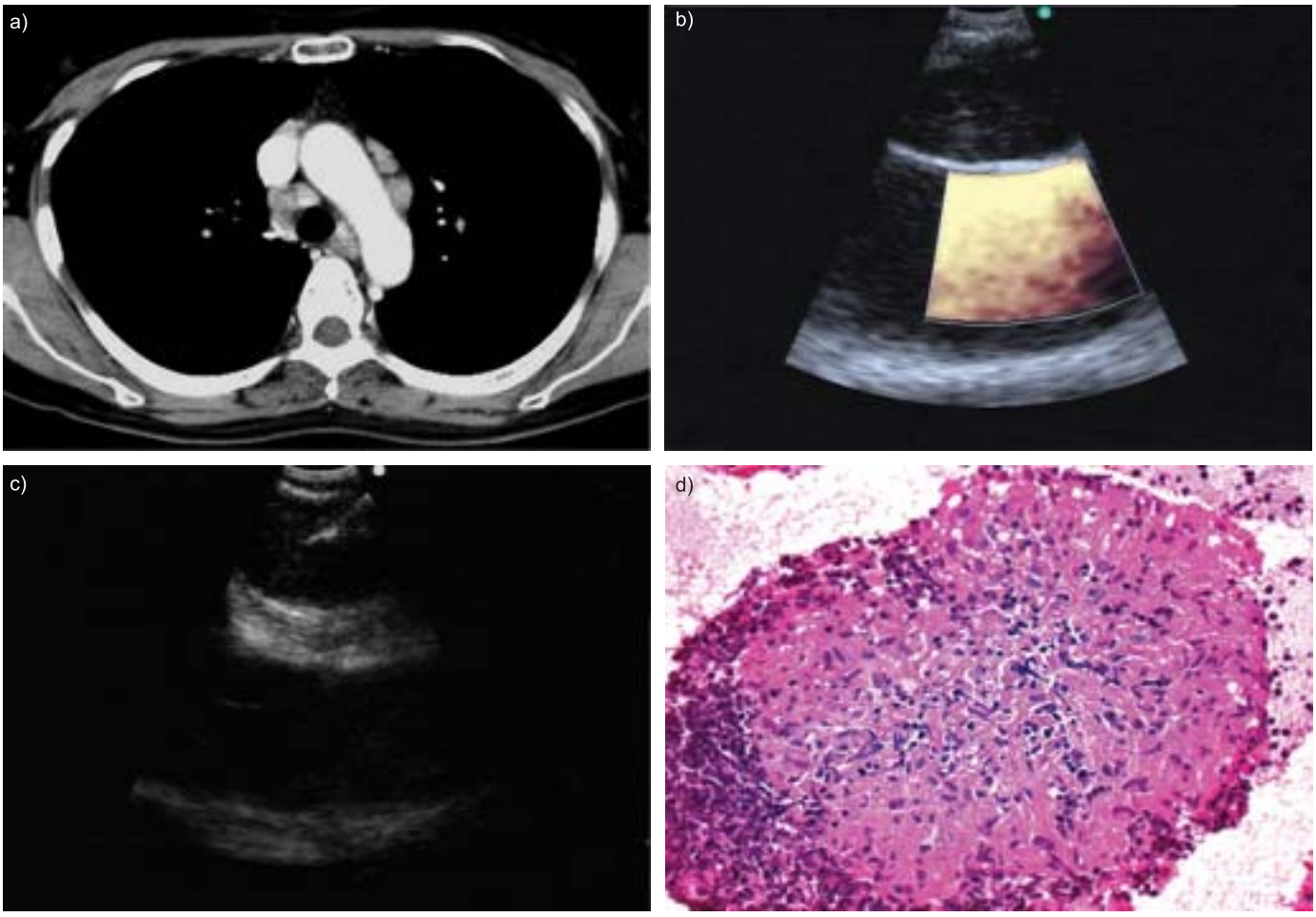

FIGURE 1. a) Computed tomography of the chest showing right lower paratracheal and subaortic lymph node enlargement. b) Endobronchial ultrasonography (EBUS) of the right lower paratracheal lymph node sitting on top of the superior vena cava, confirmed by the colour Doppler signal. c) Convex-probe EBUS-guided transbronchial needle aspiration of the same area, showing the needle within the lymph node. d) Histological specimen, demonstrating a noncaseating granuloma without necrosis, as seen in sarcoidosis.

Inadequate specimens were obtained from three patients. One of them underwent video-assisted thoracoscopic surgery, which showed Wegener's granulomatosis; another underwent mediastinoscopy, which confirmed sarcoidosis; and the final one underwent no further invasive investigation as the patient's condition had been improving (fig. 2). Two patients provided adequate specimens that showed only nonspecific reactive changes. These three patients with indefinite diagnosis were followed up for $\geqslant$18 months and showed no clinical or radiological deterioration. No patient diagnosed with sarcoidosis in the present trial required amendment of the final diagnosis during follow-up. Microbiological evaluations for tuberculosis or fungal infection all gave negative results.

Among the patients with a final diagnosis of sarcoidosis, EBUS-TBNA was diagnostic in 56 (87.5%) out of 64 patients, assuming that the three patients with indefinite diagnosis also had sarcoidosis. TBLB was performed in 51 (78%) patients, and the 11 who gave negative TBLB results gave positive EBUS-TBNA results, whereas only two patients gave positive TBLB but negative EBUS-TBNA results. The remaining five patients were confirmed as having sarcoidosis by mediastinoscopy. There were no complications due to pneumothorax, pneumomediastinum or excessive bleeding. Patients were followed up clinically and radiologically over this period.

DISCUSSION

Pathological specimens are crucial in substantiating a diagnosis of sarcoidosis and excluding other diagnoses, such as tuberculosis, Hodgkin's lymphoma and malignancy, particularly when systemic steroids are contemplated [3]. TBLB is the recommended procedure in most cases [2]. However, it is a procedure with suboptimal yield and a mean diagnostic rate of 65% (range 40–90) [11, 12], and is also associated with an appreciable complication rate; up to 10 and 5.4% of patients showed pneumothorax and pulmonary haemorrhage, respectively [4]. Added to this, the realistic diagnostic yield is somewhat lower than reported as the recommended number of biopsy specimens is often not achieved. In the present study, it was shown that the diagnostic yield of EBUS-TBNA reached 87.5%, with no complications noted. This figure takes into account the fact that the three patients classified as being of indefinite diagnosis ultimately had sarcoidosis (*i.e.* false negatives). The commonest mode of presentation of sarcoidosis is hilar and mediastinal lymphadenopathy, and up to 90%

TABLE 1 Characteristics of lymph nodes sampled by endobronchial ultrasound-guided transbronchial needle aspiration

Station	Samples	Size mm
2R	11	20.5 (11–34)
2L	7	16.1 (11–21)
4R	16	15.8 (7–26)
4L	4	20.3 (17–26)
7	29	22.4 (16–34)
10R	2	29.0 (19–37)
10L	3	19.7 (16–23)
11R	4	13.0 (9–18)
11L	1	19.0 (19–19)
Mediastinal	67	
Hilar or lobar	10	
Total	77	20.5 (7–37)

Data are presented as n or mean (range). R: right; L: left.

of patients show evidence of hilar node enlargement on chest radiography [3]. Tissue diagnosis using these areas is, therefore, reasonable, as they are a likely target for confirming the diagnosis, especially since TBLB yielded 30% of patients with undiagnosed suspected sarcoidosis [13]. The diagnostic yield of TBLB depends upon skill, number of biopsy samples taken and degree of interstitial involvement at the time of biopsy [14–16]. Optimal results can only be achieved if up to 10 biopsy specimens are taken for stage I disease and four or five for stage II disease [11, 17]. The risk of complications increases proportionally with the number of biopsy specimens needed.

TBNA was shown to have a diagnostic yield of 42–76% for sarcoidosis, with higher yield in stage I disease [18–20]. However, it is performed *via* blind needle aspiration, guided by prior CT imaging. TBNA is often underutilised, although it is useful in the diagnosis and staging of pulmonary malignancy. In the USA, only 54% of pulmonologists used TBNA in 2000, and this low percentage was mainly attributed to the perceived difficulty of this technique [21]. The results of this survey were further confirmed by another trial in which the successful yield of TBNA could only be increased from 21.4 to 47.6% after a 3-yr period of training [22]. Conversely, the accuracy of EBUS-TBNA in mediastinal staging in lung cancer could be as high as 89% for the first 20 cases [23]. Information regarding TBNA in the setting of sarcoidosis is not even mentioned as a diagnostic tool in the American Thoracic Society statement on the disease [2].

Mediastinoscopy has a high diagnostic rate and, therefore, has been the procedure of choice when TBLB is futile [2, 5]. Nonetheless, it is not without limitations. Some intrathoracic lymph nodes (*e.g.* perihilar lymph nodes, which are typical features of stage I and II sarcoidosis) are inaccessible. In the present study, the largest enlarged lymph node, with a mean size of 29 mm (range 19–37), was located in the hilar region (table 1), which may provide a better target for needle puncture and subsequently a lower risk of complications. Although only 10 out of 77 (13%) lymph nodes were located extra-mediastinally, at least some of these patients might require surgical exploration in the absence of EBUS-TBNA. Furthermore, it is almost impossible to repeat the procedure in the same patient. Generally, sarcoidosis exhibits a particular proclivity for adults aged <40 yrs [3], and mediastinoscopy inevitably leaves scars over the neck in these young people.

The recent advances in the endoscopic sampling of mediastinal lymph nodes using EBUS-TBNA and endoscopic ultrasound (EUS)-guided fine needle aspiration (EUS-FNA) have been further developed for the diagnosis and staging of lung cancer or mediastinal lymphadenopathy [13, 23]. With a higher diagnostic yield and minimal complications, EUS-FNA has been used in the diagnosis of mediastinal lymphadenopathy in benign disease. Recent trials of EUS-FNA in sarcoidosis showed a diagnostic value of 82% [13], sensitivity of 89–100% and specificity of 94–96% [24, 25]. Lymphadenopathies in sarcoidosis are typically hilar, and involvement of right paratracheal and aorto-pulmonary window lymph nodes is common (70–76%) [26]. EBUS-TBNA is able to sample stations that may be difficult to reach by mediastinoscopy, such as hilar nodes and posterior carinal nodes. Conversely, it has been shown that the right-sided paratracheal and hilar lymph nodes (2R, 4R and 10R) are better reached using the transbronchial approach (EBUS) rather than the trans-oesophageal approach (EUS), which can be explained by the fact that the oesophagus is commonly located more to the left of the trachea [27]. This preference for sampling the right-sided paratracheal station has been gauged from the experience of mediastinal lung cancer staging, in which the left paratracheal approach is known to be associated with the worst yields and major complications [28, 29]. Usually, EUS-FNA is incapable of reaching lymph nodes located in the anterior mediastinum and the rest of the thorax beyond the mediastinum. A previous report has revealed difficulty in assessing the fibrotic lymph nodes in stage II

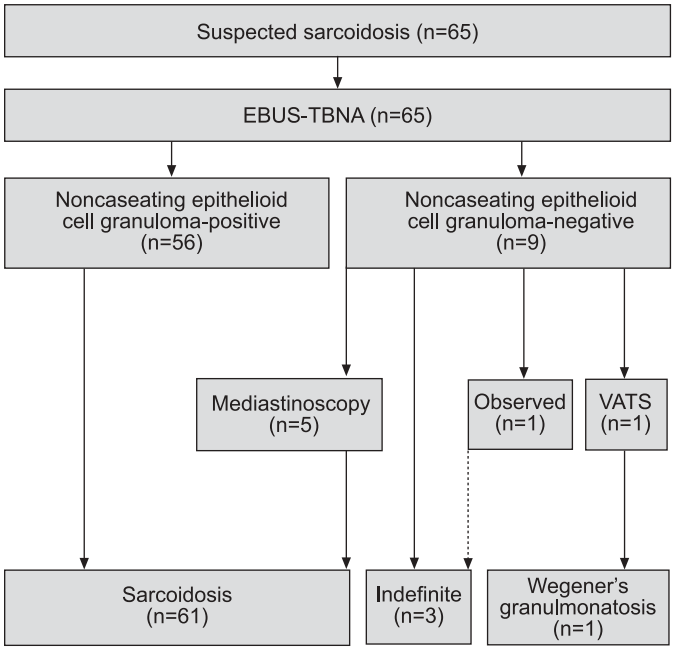

FIGURE 2. Patients suspected of having sarcoidosis were subjected to a diagnostic algorithm. Patients denoted indefinite were followed up but did not receive a specific final diagnosis. EBUS-TBNA: Real-time endobronchial ultrasound-guided transbronchial needle aspiration; VATS: video-assisted thoracoscopic surgery.

disease using the EUS-FNA approach [13]. However, this problem was not encountered in the present study.

One further advantage of EBUS-TBNA over EUS-FNA lies in the fact that EBUS-TBNA can be performed using conventional bronchoscopy with bronchoalveolar lavage, with or without TBLB, such that peripheral parenchymal, endobronchial and mediastinal lesions can be assessed in the same bronchoscopy setting, without the need for further referral, hence saving time and cost.

The limitations of the present study reflect the inherent nature of sarcoidosis. The high pre-test probability of the disease in the current study population (94%) could, therefore, have led to bias in this high diagnostic yield. The diagnosis of sarcoidosis can be difficult and relies considerably upon other examinations for the exclusion of other diseases. Tuberculosis is an epidemic disease in Japan, but this situation is confused by the spontaneous remission course of sarcoidosis, since a patient with sarcoidosis may seem to respond to empirical anti-tuberculosis treatment, further confounding the diagnosis of sarcoidosis. As the present study was originally designed to evaluate patients with hilar and/or mediastinal lymph node enlargement, the results obtained here cannot be applied directly to stage III or IV sarcoidosis.

It is envisaged that this accurate, steerable-yet-safe technique may have the potential to serve as an indispensable diagnostic tool in patients suspected of having sarcoidosis, and obviate the need for invasive procedures, with obvious cost-effectiveness implications

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AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:31620 Tracking Number

Original Specialty Recommended RVU: **2.00**
Presented Recommended RVU: **2.00**
RUC Recommended RVU: **1.50**

Global Period: ZZZ

CPT Descriptor: Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A patient has a 1.5 cm lymph node abutting the lower trachea. The node is sampled with endobronchial ultrasound assistance.

Percentage of Survey Respondents who found Vignette to be Typical: 93%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 66%

Is moderate sedation inherent to this procedure in the office setting?
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: NA

Description of Intra-Service Work:
After the diagnostic bronchoscopy, the standard bronchoscope is removed and the flexible linear convex probe linear array bronchoscope is inserted via the mouth. Use of a 30 degree angulation camera is employed to visualize the airway and identify airway structure. An assessment of the contralateral hilum and mediastinum begins with interrogation of the right hilum, the contralateral mediastinum and the subcarinal lymph node stations to assess for other pathology prior to evaluating the known lesion. This occurs when the convex portion of the scope is guided sequentially, starting with the right hilum to each nodal station and contact is made with the airway. A balloon is inflated with saline to assist with visualization. Normal structures including vasculature are identified and the scope is advanced or rotated to localize the hilar lymph nodes down to the lowest extent of the right lower lung accessible. The physician toggles back and forth between ultrasound and endoscopic views for points of reference. Vasculature is assessed with Doppler to help delineate node or vessel. If no lymph nodes are noted or enlarged, no biopsies are performed. This process is repeated at the right paratrachea. The scope is placed at the right main stem bronchus and pulled back to identify the station 10 lymph nodes then the azygous vein is identified and confirmed with Doppler. Assessment of the right paratracheal space beginning at the lower station 4 concludes when the vena cava and overlap of the subclavian and high paratrachea (station 2 nodes) above the subclavian are clear. The subcarinal node is interrogated from either the left or right mainstem looking medially, anteriorly and posteriorly identifying the overriding pulmonary artery, the esophagus and heart structures. A similar process is used to evaluate the left hilar structures. When it has been confirmed that the other stations do not require biopsy, the left paratracheal abnormality is identified typically between the aorta and left pulmonary artery. When the enlarged lymph node is identified a biopsy is performed with a dedicated endobronchial ultrasound transbronchial needle. The needle is advanced into the channel and locked it into place. The outer sheath and depth of needle throw are adjusted and confirmed

as visible at the edge of the video screen. This is tightened with a screw lock. An ultrasound image is taken for the patient's record. The EBUS scope is used to locate the target and line up the needle insertion site as indicated by the reference marker (e.g. Blue dot) on the ultrasound screen. Biopsy then commences. Multiple passes are performed after which the bronchoscope is removed.

Description of Post-Service Work: NA

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014		
Presenter(s):	Katina Nicolacakis MD (ATS), Alan Plummer, MD (ATS), Robert DeMarco, MD (ACCP), Burt Lesnick (ACCP) and Kevin Kovitz, MD (ACCP)		
Specialty(s):	American Thoracic Society (ATS) and American College of Chest Physicians (ACCP)		
CPT Code:	31620		
Sample Size:	11403	**Resp N:** 256	**Response:** 2.2 %
Description of Sample:	Combination of random & targeted sample approved by AMA RUC research committee. The targeted group included those not already in the random list & attended an ACCP educational program on the topic of EBUS. Detailed results for the total, plus the random & targeted group are included in the RUC Excel summary attached.		

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	3.00	12.00	**20.00**	53.00	300.00
Survey RVW:	0.30	1.50	**2.00**	2.00	6.75
Pre-Service Evaluation Time:			**0.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	10.00	40.00	**50.00**	60.00	180.00

Immediate Post Service-Time:	**0.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category) ZZZ Global Code

CPT Code:	31620	**Recommended Physician Work RVU: 1.50**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**0.00**	**0.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**40.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time) ZZZ Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
31633	ZZZ	1.32	**RUC Time**

CPT Descriptor Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), each additional lobe (List separately in addition to code for primary procedure)

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
99292	ZZZ	2.25	**RUC Time**	439,301

CPT Descriptor 1 Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
		0.00		

CPT Descriptor 2

Other Reference CPT Code	Global	Work RVU	Time Source
48400	ZZZ	1.95	**RUC Time**

CPT Descriptor Injection procedure for intraoperative pancreatography (List separately in addition to code for primary procedure)

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 88 **% of respondents:** 34.3 **%**

TIME ESTIMATES (Median)	**CPT Code: 31620**	**Key Reference CPT Code:** 31633	**Source of Time** RUC Time

Median Pre-Service Time	0.00	0.00
Median Intra-Service Time	40.00	20.00
Median Immediate Post-service Time	0.00	0.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**40.00**	**20.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)

		(of those that selected Key Reference code)
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	4.03	4.14
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.81	3.81
Urgency of medical decision making	3.91	3.68
Technical Skill/Physical Effort (Mean)		
Technical skill required	4.55	3.83
Physical effort required	4.09	3.57
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	3.32	4.36
Outcome depends on the skill and judgment of physician	3.38	3.51
Estimated risk of malpractice suit with poor outcome	4.14	3.44

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	0.00	0.00
Intra-Service intensity/complexity	4.11	3.78
Post-Service intensity/complexity	0.00	0.00

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

As a result of the RUC Relativity Assessment Workgroup (RAW), CPT 31620 (*Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s))* was identified at the October 2013, meeting as part of the High Volume Growth Services where Medicare utilization increased by at least 100% from 2006 to 2011. The RUC requested that these services be surveyed for physician work and develop practice expense inputs for the January 2014 RUC meeting.

31620 Compelling Evidence Statement

The performance including indications, technique and equipment for Endobronchial Ultrasound has evolved since CPT 31620 was last surveyed and evaluated by the RUC in 2004. In contrast to the previously RUC accepted physician work from 2004, there is now more physician work in the following ways:

(1) Technique

(a) Currently there is a separate bronchoscope that has the EBUS probe built into the tip. This is the standard technique for obtaining EBUS guided biopsies from mediastinal and hilar locations.
(b) The technique for using the newer bronchoscope requires the acquisition of new skills as the camera is at a 30 degree angle from the tip of the scope. The operator has to navigate the bronchoscope looking at the airway from an angle rather than the end of the scope.
(c) The ultrasound is visualized in real time during the biopsy procedure, and needs to be continuously adjusted in the field of view. This is a change from the prior technique in which the target was visualized and then the ultrasound (US) catheter removed to allow for the biopsy needle/forceps to be inserted into the same channel.

(2) The standardized procedure now involves the following:

(a) New equipment as noted above.
(b) New skills to operate the equipment.
(c) New indications as guidelines indicate it is the initial best test for staging the mediastinum for lung cancer.
(d) New indications as EBUS can be utilized for diagnosing nonmalignant pulmonary diseases and infections.

We believe that the median results on the 2013 AMA RUC Survey Data of EBUS, which increased to 2.00 RVWs, correctly placed the physician work compared to those services listed in the table located in the additional rationale of this summary of recommendations.

References

Almeida FA, Casal RF, Jimenezs CA, et al. Quality Gaps and Comparative Effectiveness in Lung Cancer Staging, Chest. December 2013;144(6):1776-1782.

Manaker S, Vachani A, The Changing Face of Outpatient Bronchoscopy. Chest. May 2013; 2013; 143(5):1214-1218.

Wong M, Yasafuku K et al. Endobronchial Ultrasound: New Insight for the Diagnosis of Sarcoidosis. Eur Resp J 2007; 29: 1182-1186.

Survey Results & ATS/ACCP Recommendations:
31620

A joint multi-society expert panel from the American Thoracic Society (ATS) and American College of Chest Physicians (ACCP), herein referred to as the ATS/ACCP expert panel, convened for a call and over e-mail to review and discuss the survey results. The ATS/ACCP panel was pleased that there were a total of 256 responses to the survey requests. Two survey pools were used. The first pool was a standard random sample from both societies de-duplicating the members so any potential participant only received one survey request. The second targeted pool was sent to 230 de-duplicated from the random pools for participants of an ACCP educational program for EBUS services. The targeted group and the method for identification to the RUC were approved by the AMA research committee in advance of the survey. The RUC Excel summary reports the data from the two separate survey pools, the random, the targeted as well as the data for the total. The data used for this SoR is the combination of the two survey pools, both random and targeted. The survey performance rate median of 30 studies per year among the 256 respondents is a reasonable rate given this is a relatively low volume procedure.

- The survey yielded 256 responses spread appropriately among the participating specialties. This is a very robust response with very tight data.
- 93% of respondents found the vignette to be typical.
- 66% of respondents said that this service was typically performed in the Hospital ASC setting with moderate sedation.
- 65% of the respondents said that this service was not provided in the office setting.

Based on these observations and the rest of the survey results, the expert panel is recommending the following with respect to physician time and work.

Time:
The ATS/ACCP expert panel agreed that the survey median intra-service time of 50 minutes accurately reflects the time required to perform this service today. As compared to the last time this service was reviewed by the RUC in 2004, the procedure has changed significantly. There is new equipment being utilized with a separate bronchoscope now that includes the US at the tip, instead of a catheter radial probe that was previously inserted through the working channel of the standard flexible bronchoscope. In addition, the technology and therefore the procedure has also changed which is described in the intraservice work. Now there is a methodical assessment of multiple lymph node stations prior to commencing with biopsies of the lymph node in question. As this is an add-on service, we selected pre-service package ZZZ with 0 pre-time and 0 post-time. The current time for 31620 is 20 minutes, which our expert panel agrees is an outdated time. The 20 minutes was established from a RUC survey conducted in 2004 when the technology and methods were different, and the utilization minimal. Please see the compelling evidence arguments for details regarding the changes to support the survey median results. Additionally the 2004 survey consisted of 18 respondents, a far different response rate from 256 respondents in 2013. After review of the survey data and discussion with our experts, the expert panel is recommending our survey median intra-service time of 50 minutes with 0 pre and 0 post time for CPT 31620.

Work:
Survey respondents estimated a median work RVU of 2.00, based on a comparison to the key reference service. The survey results supported the reference service code chosen by the majority of the survey respondents, CPT 31633 *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), each additional lobe* (RVW 1.32) to have a lower time work intensity and complexity than 31620, and as the survey correctly reflects, 31620 has a higher skill and physical effort mental effort, while the judgment is similar or lower intensity.

The expert panel compared 31620 to a MPC code CPT 99292 Global ZZZ (*Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes),* (RVW 2.25, times 0-30-0, total 30 min). Other MPC codes that are not ZZZ codes, but also comparable include: CPT 94002 Global XXX (*Ventilation assist and management,*

initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, initial day), (RVW 1.99, times 15-30-15, total 60 min). MPC codes CPT 99233 Global XXX (*Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit),* (RVW 2.00, times 10-30-15, total 55 min), MPC CPT 74178 Global XXX (*Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions),* (RVW 2.01, times 5-30-5, total 40 min). While we believe these procedures are comparable in intensity and complexity the ATS/ACCP panel would agree that 31620 should be valued lower than 99292 (RVW 2.25) and similar to CPT 94002, 99233 and 94178 (RVWs 1.99, 2.00 and 2.01 respectively.)

Code	Short Description	Global Period	Pre-Service	Intra-Service	Post-Service	Total Time	Work RVU	IWPUT
99356	Prolonged service inpatient	ZZZ	0	60	0	60	1.71	0.0285
19297	Place breast cath for rad	ZZZ	5	30	5	40	1.72	0.0499
99354	Prolonged service office	ZZZ	0	60	0	60	1.77	0.0295
90836*	Psytx pt&/fam w/e&m 45 min	ZZZ	0	45	3	48	1.90	0.0341
48400	Injection intraop add-on	ZZZ	0	45	0	45	1.95	0.0433
43273	Endoscopic pancreatoscopy	ZZZ	0	45	0	45	2.24	0.0498
22116	Remove extra spine segment	ZZZ	0	45	0	45	2.32	0.0516
22522	Percut vertebroplasty addl	ZZZ	0	50	0	50	4.30	0.0860

*Note values for time and RVW from CY 2014 final rule published November 27, 2013.

In summary, we recommend a RVW of 2.00 for 31620 with a pre service time 0 minutes, intra service time 50 minutes and post time 0 minutes.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: Yes

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☒ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your

scenario. Typically reported with CPT 31629 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 31620

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Pulmonary How often? Sometimes

Specialty Critical Care How often? Rarely

Specialty Thoracic Surgery How often? Rarely

Estimate the number of times this service might be provided nationally in a one-year period? 53868
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. RUC database 2012 Medicare utilization multiplied by 3.

Specialty Pulmonary Frequency 38500 Percentage 71.47 %

Specialty Thoracic Surgery Frequency 5000 Percentage 9.28 %

Specialty Critical Care Frequency 4000 Percentage 7.42 %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 17,921 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. RUC database 2012 Medicare utilization.

Specialty Pulmonary Frequency 12800 Percentage 71.28 %

Specialty Thoracic Surgery Frequency 1700 Percentage 9.46 %

Specialty Critical Care Frequency 1400 Percentage 7.79 %

Do many physicians perform this service across the United States? No

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Endoscopy

BETOS Sub-classification Level II:
Bronchoscopy

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 31620

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

ISSUE: Endobronchial Ultrasound

TAB: 22

Source	CPT	Short DESC	Resp	IWPUT	RVW MIN	RVW 25th	RVW MED	RVW 75th	RVW MAX	Total Time	PRE EVAL	INTRA MIN	INTRA 25th	INTRA MED	INTRA 75th	INTRA MAX	IMMD POST	SURVEY EXPERIENCE MIN	SURVEY EXPERIENCE 25th	SURVEY EXPERIENCE MED	SURVEY EXPERIENCE 75th	SURVEY EXPERIENCE MAX
Key REF	31633	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), each additional lobe	88	0.0660			1.32			20				20								
CURRENT	31620	Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s)	18	0.0700			1.40			20				20								
SVY-Targeted Data	31620	Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s)	13	0.0333	1.00	1.48	2.00	2.37	6.75	60		30	45	60	105	180		3	12	20	53	300
SVY-Random	31620	Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s)	243	0.0400	0.30	1.50	2.00	2.00	5.00	50		10	35	50	60	180		0	14	30	80	700
SVY-Random + Targeted	31620	Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s)	256	0.0400	0.30	1.50	2.00	2.00	6.75	50		10	40	50	60	180		0	13	30	78	700
REC	31620	Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s)		0.038			1.50			40				40								

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:

Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure(s))

Global Period: _ZZZ__ Meeting Date: _January 2014_____

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:
The ATS and ACCP convened a consensus panel via telephone and email to develop the inputs for this code.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes.

Reference Base Code Rationale: The surveying societies agreed upon CPT 31629 *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)* as the reference base code based upon the direct PE inputs and because it is the most likely code to be billed in conjunction with 31620.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:

As a result of the RUC Relativity Assessment Workgroup (RAW), CPT 31620 (*Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s))* was identified at the October 2013, meeting as part of the High Volume Growth Services where Medicare utilization increased by at least 100% from 2006 to 2011. The RUC requested that these services be surveyed for physician work and develop practice expense inputs for the January 2014 RUC meeting.

31620 Compelling Evidence Statement

The performance including indications, technique and equipment for Endobronchial Ultrasound has evolved since CPT 31620 was last surveyed and evaluated by the RUC in 2004. In May of 2013 the American College of Chest Physicians (ACCP) published updated guidelines[1] on the Diagnosis and Management of Lung Cancer. This newest guideline establishes the standard for

[1] Chest Diagnosis and Management of Lung Cancer, 3rd ED: ACCP Guidelines, CHEST 2013; 143(5)(suppl):e211S-e250S

diagnosing and staging lung cancer. In selected patients with suspicion of mediastinal spread, either by discrete mediastinal lymph node enlargement on CT or PET uptake (and no distant metastases), a needle technique (endobronchial ultrasound [EBUS]-needle aspiration [NA], EUS-NA or combined EBUS/EUS-NA) is recommended over surgical staging as a best first test (Grade 1B). EBUS directed transbronchial needle aspiration is also now used to diagnose nonmalignant pulmonary diseases, such as sarcoidosis, tuberculosis and other infections as well with a growing body of literature to support this as the first test in patients with lymphadenopathy in the mediastinum.

In contrast to the previously RUC accepted physician work from 2004, there is now more physician work in the following ways:

(1) Technique

(a) Currently there is a separate bronchoscope that has the EBUS probe built into the tip. This is the standard technique for obtaining EBUS guided biopsies from mediastinal and hilar locations.

(b) The technique for using the newer bronchoscope requires the acquisition of new skills as the camera is at a 30 degree angle from the tip of the scope. The operator has to navigate the bronchoscope looking at the airway from an angle rather than the end of the scope.

(c) The ultrasound is visualized in real time during the biopsy procedure, and needs to be continuously adjusted in the field of view. This is a change from the prior technique in which the target was visualized and then the ultrasound (US) catheter removed to allow for the biopsy needle/forceps to be inserted into the same channel.

(2) The standardized procedure now involves the following:

(a) New equipment as noted above.

References

Almeida FA, Casal RF, Jimenezs CA, et al. Quality Gaps and Comparative Effectiveness in Lung Cancer Staging, Chest. December 2013;144(6):1776-1782.

Manaker S, Vachani A, The Changing Face of Outpatient Bronchoscopy. Chest. May 2013; 2013; 143(5):1214-1218.

Wong M, Yasafuku K et al. Endobronchial Ultrasound: New Insight for the Diagnosis of Sarcoidosis. Eur Resp J 2007; 29: 1182-1186.

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:

(Line 30 and 31) Increased time consistent with physician work from survey estimates.
(Line 36) This is a flexible dual-channeled EBUS bronchoscope, therefore we chose the base standard of 30 minutes, we included 5 additional minutes above the standard for flexible to account for time to clean the additional channel.
(Line 75) As per the current guidelines noted in our compelling evidence the national standard is 5L/M and based on the time from our survey the use of oxygen was increased to 250 Liters.

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

N/A.
Intra-Service Clinical Labor Activities:

Prepare flexible dual-channeled EBUS bronchoscope and necessary supplies.
Administer and monitor additional conscious sedation.
Assist physician in performing procedure. Adjusting endoscopic image(s) versus ultrasound image(s), as necessary.
Clean flexible dual-channeled EBUS bronchoscope (100% of scope cleaning time).

Post-Service Clinical Labor Activities:

N/A

	A	B	C	D	E	F	G	H	I
1				REFERENCE CODE		REFERENCE CODE			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**CPT Code # 31629 (Base Service)**		**CPT Code # 31620 (ADD On Code - 2014 Inputs)**		**CPT Code # 31620**	
3	**Meeting Date: January 2014 - 1-21-2014 version** **Tab: 22 EBUS** **Specialty: ATS and ACCP**	**CMS Code**	**Staff Type**	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)		Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])		Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])	
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**			**000**	**000**	**ZZZ**	**ZZZ**	**ZZZ**	**ZZZ**
6	**TOTAL CLINICAL LABOR TIME**			**164.0**	**15.0**	**47.0**	**0.0**	**117.0**	**0.0**
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**18.0**	**15.0**	**0.0**	**0.0**	**0.0**	**0.0**
8	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**146.0**	**0.0**	**47.0**	**0.0**	**117.0**	**0.0**
9	**TOTAL POST-SERV CLINICAL LABOR TIME**			**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
10	**PRE-SERVICE**								
11	**Start: Following visit when decision for surgery or procedure made**								
12	Complete pre-service diagnostic & referral forms	L047C	RN/RT	**5**	**5**				
13	Coordinate pre-surgery services	L047C	RN/RT	**3**	**5**				
14	Schedule space and equipment in facility	L047C	RN/RT	**0**	**3**				
15	Provide pre-service education/obtain consent	L047C	RN/RT	**7**	**0**				
16	Follow-up phone calls & prescriptions	L047C	RN/RT	**3**	**2**				
17	*Other Clinical Activity - *specify:*								
18	**End: When patient enters office/facility for surgery/procedure**								
19	**SERVICE PERIOD**								
20	**Start: When patient enters office/facility for surgery/procedure:**								
21	Greet patient, provide gowning, ensure appropriate medical records are available	L047C	RN/RT	**3**					
22	Obtain vital signs	L047C	RN/RT	**5**					
23	Provide pre-service education/obtain consent								
24	Prepare room, equipment, supplies	L047C / L042B	RN/RT	**2**		**2**		**2**	
25	Setup scope (non facility setting only)	L047C	RN/RT	**5**					
26	Prepare and position patient/ monitor patient/ set up IV	L047C	RN/RT	**2**					
27	Sedate/apply anesthesia	L051A	RN	**2**					
28	*Other Clinical Activity - specify: Review Charts	L047C	RN/RT	**2**					
29	**Intra-service**								
30	Assist physician in performing procedure	L047C / L042B	RN/RT	**30**		**20**		**40**	
31	Assist physician/moderate sedation (% of physician time)	L051A	RN	**30**		**20**		**40**	
32	**Post-Service**								
33	Monitor pt. following moderate sedation								
34	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L051A	RN	**25**					
35	Clean room/equipment by physician staff	L047C	RN/RT	**3**					
36	Clean Scope	L047C / L042B	RN/RT	**30**		**5**		**35**	
37	Clean Surgical Instrument Package								
38	Complete diagnostic forms, lab & X-ray requisitions	L047C	RN/RT	**4**					
39	Review/read X-ray, lab, and pathology reports								
40	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	L047C	RN/RT	**3**					
41	*Other Clinical Activity - *specify:*								
42	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)			**n/a**		**n/a**		**n/a**	
43	Dischrg mgmt (1.0 x 99238) (enter 12 min)			**n/a**		**n/a**		**n/a**	
44	Dischrg mgmt (1.0 x 99239) (enter 15 min)			**n/a**		**n/a**		**n/a**	
45	**End: Patient leaves office**								
46	**POST-SERVICE Period**								
47	**Start: Patient leaves office/facility**								
48	Conduct phone calls/call in prescriptions								
49	**End: with last office visit before end of global period**								

	A	B	C	D	E	F	G	H	I
1				REFERENCE CODE		REFERENCE CODE			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**CPT Code # 31629 (Base Service)**		**CPT Code # 31620 (ADD On Code - 2014 Inputs)**		**CPT Code # 31620**	
3	**Meeting Date: January 2014 - 1-21-2014 version** **Tab: 22 EBUS** **Specialty: ATS and ACCP**	**CMS Code**	**Staff Type**	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)		Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])		Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])	
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**			**000**	**000**	**ZZZ**	**ZZZ**	**ZZZ**	**ZZZ**
50	**MEDICAL SUPPLIES****	**CODE**	**UNIT**						
51	pack, minimum multi-specialty visit	SA048	pack	**1**					
52	pack, cleaning and disinfecting, endoscope	SA042	pack	**1**					
53	pack, moderate sedation	SA044	pack	**1**					
54	needle, transbronchial, cytology (Wang)	SC043	item	**3**					
55	syringe 10-12ml	SC051	item	**2**					
56	syringe 50-60ml	SC056	item	**2**					
57	suction specimen trap, sterile	SD121	item	**1**					
58	gauze, sterile 4in x 4in (10 pack uou)	SG056	item	**2**					
59	lidocaine 1%-2% inj (Xylocaine)	SH047	ml	**40**					
60	lidocaine 2% jelly, topical (Xylocaine)	SH048	ml	**5**					
61	lidocaine 4% soln, topical (Xylocaine)	SH050	ml	**20**					
62	sodium chloride 0.9% inj (10ml uou)	SH066	item	**1**					
63	basin, emesis	SJ010	item	**1**					
64	denture cup	SJ016	item	**1**					
65	cup, biopsy-specimen sterile 4oz	SL036	item	**2**					
66	eye shield, splash protection	SM016	item	**2**					
67	gas, oxygen	SD084	liter			**40**		**250 L**	
68	sheath, endoscope ultrasound balloon	SD205	item			**1**			
69	MAJ-1351 BALLOON FOR BF-UC160F-OL8	Invoice	item					**1**	
70	**EBUS, single use aspiration needle, 21 g**	**Invoice**	item					**1**	
71	**EQUIPMENT**	**CODE**							
72	fiberscope, flexible, bronchoscopy	ES017		**116**		**20**		**40**	
73	video system, endoscopy (processor, digital capture, monitor, printer, cart)	ES031		**116**		**20**		**40**	
74	suction machine (Gomco)	EQ235		**116**		**20**		**40**	
75	IV infusion pump	EQ032		**132**		**20**		**40**	
76	ECG, 3-channel (with SpO2, NIBP, temp, resp)	EQ011		**132**		**20**		**40**	
77	fluoroscopic system, mobile C-Arm	ER031		**116**					
78	table, power	EF031		**116**		**20**		**40**	
79	table, instrument, mobile	EF027		**132**		**20**		**40**	
80	endoscope, ultrasound probe, balloon sheath	ES014				**27**			
81	endoscope, ultrasound probe, drive	ES015				**27**			
82	endoscope, ultrasound probe, processor and keyboard	ES016				**27**			
83	**Flexible dual-channeled EBUS bronchoscope, with radial probe**	**Invoice**						**77**	
84	**Video system, Ultrasound (processor, digital capture, monitor, printer, cart)**	**Invoice**						**40**	

AMA/Specialty Society RVS Update Committee Summary of Recommendations
New Technology/New Services List

January 2014

Bronchoscopy-Computer Assisted- PE Only -Tab 23

CPT code 31627 *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation* was identified through the New Technology/New Services List in February 2009. In October 2013, the Relativity Assessment Workgroup noted there may have been diffusion in technology for this service and requested that the practice expense direct inputs be reviewed at the January 2014 meeting and that the RAW review the data again in 3 years (September 2016). **The RUC reviewed and approved the direct practice expense inputs without modification as approved by the Practice Expense Subcommittee.**

CPT Code (•New)	Tracking Number	CPT Descriptor	Global Period	Work RVU Recommendation
31627		Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s]) (31627 includes 3D reconstruction. Do not report 31627 in conjunction with 76376, 76377) (Use 31627 in conjunction with 31615, 31622-31631, 31635, 31636, 31638-31643)	ZZZ	PE Input Recommendation Only

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

Revised 1-22-2014
CPT Long Descriptor:

Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])

Global Period: _ZZZ__ Meeting Date: _January 2014_____

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:
The ATS and ACCP convened a consensus panel via telephone and email to develop the inputs for this code.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Base Code Rationale: The surveying societies agreed upon CPT 31628 *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe* as the reference base code based upon the direct PE inputs and because it is the most likely code to be billed in conjunction with 31627.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time: N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence: N/A

(Line 74 is added, O2 is required, time based on physician time and National Standard of 5L/M.)
(Line 80 suction machine was added, add-on service requires use of suction for entire service.)
(Lines 78, 79, 83 and 84 were added, add-on service requires use of C-arm and all other equipment and table are all in use for the base code and continues through the navigation add-on service.)
(Lines 81, 82, 85, 86 were increased from 30 minutes to 45 minutes consistent with the standard to add equipment for times to prep and set up, therefore all equipment for this add on code adds lines, 24, 25, 27 and 31 for a total of 45 minutes.)

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

N/A

Intra-Service Clinical Labor Activities:

- Navigation system is prepared. Room configuration is checked/verified
- Bronchoscope is prepped with local guide catheter and endoscopic tools are marked
- Sensors are attached to the patient and patient is positioned over location board
- System operation and patient position are checked

Navigation phase

- RN assists in moderate sedation or general anesthesia of patient, when performed in OR
- Assist physician during the procedure which includes handling the locator guide, bronchoscope and breathing tube
- Monitor and manage system operations with both remote and touch screen, toggle between targets per physician instruction
- Assist in shut down of navigation system

Post-Service Clinical Labor Activities:

N/A

	A	B	C	D	E	F	G	H	I
1				REFERENCE CODE		REFERENCE CODE			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**CPT Code # 31628 (Base Service)**		**CPT Code # 31627 (ADD On Code - 2014 Inputs)**		**CPT Code # 31627**	
3	**Meeting Date: January 2014 -1-22-2014 version Tab: 23 Bronchoscopy Computer Assisted Specialty: ATS and ACCP**	**CMS Code**	**Staff Type**	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe		Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to		Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to	
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**			**000**	**000**	**ZZZ**	**ZZZ**	**ZZZ**	**ZZZ**
6	**TOTAL CLINICAL LABOR TIME**			**171.0**	**15.0**	**105.0**	**0.0**	**73.0**	**0.0**
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**18.0**	**15.0**	**0.0**	**0.0**	**0.0**	**0.0**
8	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**153.0**	**0.0**	**105.0**	**0.0**	**73.0**	**0.0**
9	**TOTAL POST-SERV CLINICAL LABOR TIME**			**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
10	**PRE-SERVICE**								
11	**Start: Following visit when decision for surgery or procedure made**								
12	Complete pre-service diagnostic & referral forms	L047C	RN/RT	**5**	**5**				
13	Coordinate pre-surgery services	L047C	RN/RT	**3**	**5**				
14	Schedule space and equipment in facility	L047C	RN/RT	**0**	**3**				
15	Provide pre-service education/obtain consent	L047C	RN/RT	**7**	**0**				
16	Follow-up phone calls & prescriptions	L047C	RN/RT	**3**	**2**				
17	*Other Clinical Activity - *specify:*								
18	**End: When patient enters office/facility for surgery/procedure**								
19	**SERVICE PERIOD**								
20	**Start: When patient enters office/facility for surgery/procedure:**								
21	Greet patient, provide gowning, ensure appropriate medical records are available	L047C	RN/RT	**3**					
22	Obtain vital signs	L047C	RN/RT	**5**					
23	Provide pre-service education/obtain consent								
24	Prepare room, equipment, supplies	L047C /L042B	RN/RT	**2**		**2**		**2**	
25	Power, System Preparation & Attaching to Bronchoscope	L042B	RT			**11**		**11**	
26	Setup scope (non facility setting only)	L047C	RN/RT	**5**					
27	Prepare and position patient/ monitor patient/ set up IV	L047C	RN/RT	**2**		**2**		**0**	
28	Sedate/apply anesthesia	L051A	RN	**2**					
29	*Other Clinical Activity - specify: Review Charts	L047C	RN/RT	**2**					
30	**Intra-service**								
31	Assist physician in performing procedure	L047C /L042B		**40**		**30**		**30**	
32	Assist physician/moderate sedation (% of physician time)	L051A	RN	**27**		**60**		**30**	
33	**Post-Service**								
34	Monitor pt. following moderate sedation								
35	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L051A	RN	**25**					
36	Clean room/equipment by physician staff	L047C		**3**					
37	Clean Scope	L047C /L042B		**30**					
38	Clean Surgical Instrument Package								
39	Complete diagnostic forms, lab & X-ray requisitions	L047C		**4**					
40	Review/read X-ray, lab, and pathology reports								
41	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	L047C		**3**					
42	*Other Clinical Activity - *specify:*								
43	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)			**n/a**		**n/a**		**n/a**	
44	Dischrg mgmt (1.0 x 99238) (enter 12 min)			**n/a**		**n/a**		**n/a**	
45	Dischrg mgmt (1.0 x 99239) (enter 15 min)			**n/a**		**n/a**		**n/a**	
46	**End: Patient leaves office**								
47	**POST-SERVICE Period**								
48	**Start: Patient leaves office/facility**								
59	**MEDICAL SUPPLIES****	**CODE**	**UNIT**						
60	pack, minimum multi-specialty visit	SA048	pack	**1**					
61	pack, cleaning and disinfecting, endoscope	SA042	pack	**1**					
62	pack, moderate sedation	SA044	pack	**1**					
63	syringe 10-12ml	SC051	item	**2**					
64	suction specimen trap, sterile	SD121	item	**1**					
65	gauze, sterile 4in x 4in (10 pack uou)	SG056	item	**2**					
66	lidocaine 1%-2% inj (Xylocaine)	SH047	ml	**40**					
67	lidocaine 2% jelly, topical (Xylocaine)	SH048	ml	**5**					
68	lidocaine 4% soln, topical (Xylocaine)	SH050	ml	**20**					
69	sodium chloride 0.9% inj (10ml uou)	SH066	item	**1**					
70	basin, emesis	SJ010	item	**1**					
71	denture cup	SJ016	item	**1**					
72	cup, biopsy-specimen sterile 4oz	SL036	item	**2**					
73	eye shield, splash protection	SM016	item	**2**					
74	Gas, oxygen	SD084	liter					**150 L**	
75	**kit, locatable guide, ext. working channel, w-b-scope adapter**	SA097	kit					**1**	
76	sensor, patch, bronchosopy (for kit, locatable guide) (patient)	SD235	kit					**3**	
77	**EQUIPMENT**	**CODE**							
78	fiberscope, flexible, bronchoscopy	ES017		**86**				**43**	
79	video system, endoscopy (processor, digital capture, monitor, printer, cart)	ES031		**86**				**43**	
80	suction machine (Gomco)	EQ235		**86**				**43**	
81	IV infusion pump	EQ032		**142**		**30**		**30**	
82	ECG, 3-channel (with SpO2, NIBP, temp, resp)	EQ011		**142**		**30**		**30**	
83	fluoroscopic system, mobile C-Arm	ER031		**86**				**43**	
84	table, power	EF031		**86**				**43**	
85	table, instrument, mobile	EF027		**142**		**30**		**30**	
86	system, navigational bronchoscopy (superDimension)	EQ326				**30**		**43**	

AMA/Specialty Society RVS Update Committee Summary of Recommendations
CMS Fastest Growing / High Volume Growth screen

January 2014

Percutaneous Implantation of Neuroelectrodes

At the October 2013, meeting the Relativity Assessment Workgroup reviewed High Volume Growth Services where Medicare utilization increased by at least 100% from 2006 to 2011. The RUC requested that these services be surveyed for physician work and develop practice expense inputs for the January 2014 RUC meeting.

64561 Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
The RUC reviewed the survey results from 83 urologists and gynecologists and determined that the survey 25th percentile work RVU of 6.88 was too high because the physician intra-service time required to perform this service had decreased 20 minutes from when it was last evaluated in 2001. Although the current work RVU for CPT code 64561 is 7.15, the Committee determined that the efficiencies gained account for a higher decrease in work RVUs. The Committee compared 64561 to MPC code 52235 *Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; MEDIUM bladder tumor(s) (2.0 to 5.0 cm)* (work RVU = 5.44 and 29 minutes pre-service, 45 minutes intra-service time and 20 minutes immediate post-service time) and recommends a direct crosswalk. This brings the intensity required to perform this service in line with other similar services. For additional support, the Committee referenced 33213 *Insertion of pacemaker pulse generator only; with existing dual leads* (090 global, work RVU = 5.53 and 46 minutes intra-service time and 1-99213). The RUC determined that 22 minutes pre-evaluation, 5 minutes positioning, 45 minutes intra-service time and 19 minutes immediate post service time and one 99214 office visit for CPT code 64561 appropriately account for the work required to perform this service. **The RUC recommends a work RVU of 5.44 for CPT code 64561.**

Work Neutrality
The RUC's recommendation for this family of codes will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

Practice Expense
The RUC recommends the direct practice expense inputs as modified by the Practice Expense Subcommittee.

CPT Code (•New)	CPT Descriptor	Global Period	Work RVU Recommendation
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed	010	5.44

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:64561 Tracking Number Original Specialty Recommended RVU: **6.88**
Presented Recommended RVU: **6.88**
Global Period: 010 RUC Recommended RVU: **5.44**

CPT Descriptor: Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 47-year-old female with intractable and debilitating urge incontinence voids hourly. All available conservative remedies have been unsuccessful. A percutaneous test stimulation is planned to determine the effectiveness of transacral neuromodulation for control of her urinary symptoms.

Percentage of Survey Respondents who found Vignette to be Typical: 87%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 40% , In the ASC 20%, In the office 39%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 100% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 42%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 25%

Description of Pre-Service Work: Pre-service Work- Day before surgery:
Review pre-op lab results
Review medical record
Check to be sure necessary equipment/supplies are in the office

Pre-service work- Day of surgery:
Review surgical procedure, post-op recovery with patient and family
Answer patient and family questions, be sure informed consent is in record
Position patient on power table
Verify that all necessary instruments are available

Description of Intra-Service Work:
Approximate levels of the sacral foramina using fluoroscopy
Anesthetize skin and periosteum over and near chosen foramen
Pass an electrically insulated 3 or 5 inch needle percutaneously into the foramen
Connect an external screener (power source) to the foramen needle by a separate cable and grounding source
Discern and document specific biologic responses to stimulation of S2 and no activity for S4
Desired responses are S2 and S3
A 3 - 0 temporary electrode is exchanged through the lumen of the foramen needle, leaving only the electrode in place
Re-testing is performed to confirm response
Dressing is placed to secure the electrode in place

Hard X-ray is done to confirm lead position

Description of Post-Service Work:
Apply dressings
Write post-op orders
Review post procedure care and medications with staff
Meet with patient and family to discuss the procedure, expected outcome, planned post operative care
Call referring physician regarding outcome of procedure and any unusual aspects of post operative care (cardiac disease, diabetic management)
Dictate detailed operative narrative
Write prescriptions for post-op medications

Post-op Office work
Examine patient, check vital signs
Review testing results and voiding diary
Remove lead and electrode from patient
Apply dressing
Talk with patient and family
Answer questions from patient and family
Write necessary prescriptions
Schedule next office visit
Mark appropriate diagnosis and CPT code on Superbill
Dictate patient progress notes for office medical record
Dictate letter to referring physician

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014				
Presenter(s):	Norm Smith, MD, Philip Wise, MD, George Hill, MD				
Specialty(s):	Urology, Obstetrics/Gynecology				
CPT Code:	64561				
Sample Size:	197	**Resp N:**	83	**Response:** 42.1 %	
Description of Sample:	Random				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	2.00	9.00	**12.00**	20.00	75.00
Survey RVW:	5.00	6.88	**7.15**	7.93	17.80
Pre-Service Evaluation Time:			**45.00**		
Pre-Service Positioning Time:			**10.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	20.00	30.00	**45.00**	60.00	90.00

Immediate Post Service-Time:	**20.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**40.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **1.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

5 - NF Procedure without sedation/anesthesia care

CPT Code:	64561	**Recommended Physician Work RVU: 5.44**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**22.00**	**7.00**	**15.00**
Pre-Service Positioning Time:		**5.00**	**0.00**	**5.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**1.00**	**-1.00**
Intra-Service Time:		**45.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

7A Local/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**19.00**	**16.00**	**3.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**40.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **1.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
63650	010	7.15	**RUC Time**

CPT Descriptor Percutaneous implantation of neurostimulator electrode array, epidural

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
55706	010	6.28	**RUC Time**	1,565

CPT Descriptor 1 Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
22524	010	8.54	**RUC Time**	25,978

CPT Descriptor 2 Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); lumbar

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 49 **% of respondents:** 59.0 **%**

TIME ESTIMATES (Median)	**CPT Code: 64561**	**Key Reference CPT Code:** 63650	**Source of Time** **RUC Time**

Median Pre-Service Time	27.00	48.00
Median Intra-Service Time	45.00	60.00
Median Immediate Post-service Time	19.00	20.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	19.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	40.0	23.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**131.00**	**170.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	4.10	4.00
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	4.24	4.12
Urgency of medical decision making	2.80	2.96
Technical Skill/Physical Effort (Mean)		
Technical skill required	4.35	4.22
Physical effort required	3.57	3.49
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	3.24	3.35
Outcome depends on the skill and judgment of physician	4.33	4.27
Estimated risk of malpractice suit with poor outcome	2.94	3.10

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	3.59	3.59
Intra-Service intensity/complexity	4.10	4.00
Post-Service intensity/complexity	3.55	3.53

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The AUA sent a "do you do letter" to a random number of AUA and American Congress of Obstetricians and Gynecologists' subspecialty: American Urogynecologic Society members. The surveys were then sent to the individual physicians who answered that they do the procedure and would complete the RUC survey. The survey was sent to 197 individuals and of those individuals, 83 responses were received for a response rate of 42.13%. In 2013, 17,771 of these procedures were performed in the Medicare population so the number of responses to this survey meets the new RUC criteria of 30 respondents as the minimum survey sample size for this code.

The AUA RUC expert panel reviewed the survey results, which confirmed that 45 minutes of intraservice time is necessary to complete this procedure. The current intraservice time is 70 minutes. The current work RVU is 7.15. The median work value from the survey is 7.15. Although the survey results state that 40% of these procedures are performed in the hospital, Medicare claims data shows that 69% of these procedures in 2013 were performed in the physicians' office. Since this procedure is done the majority of the time in the physician's office, a half day discharge is no longer required and it was determined that one 99214 should be assigned in the global period. The preservice time package 5 was chosen which reduced the preservice time from 45 minutes to 10 minutes and the postservice package 7A was chosen which reduced the postservice time from 30 minutes to 16 minutes.In addition, the RUC expert panel felt that two minutes of positioning time was appropriate for this procedure.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 64561

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Urology How often? Sometimes

Specialty OB/GYN How often? Sometimes

Specialty Colorectal Surgery How often? Rarely

Estimate the number of times this service might be provided nationally in a one-year period? 22213
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. Medicare X 125%

Specialty Urology Frequency 17641 Percentage 79.41 %

Specialty OB/GYN Frequency 4140 Percentage 18.63 %

Specialty Colorectal Surgery Frequency 81 Percentage 0.36 %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 17,771 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. RUC Database

Specialty Urology Frequency 14113 Percentage 79.41 %

Specialty OB/GYN Frequency 3312 Percentage 18.63 %

Specialty Colorectal Surgery Frequency 65 Percentage 0.36 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Major procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 64561

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

SS Rec Summary

ISSUE: 64561 Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed

TAB: 25

Source	CPT	DESC	Resp	IWPUT	RVW MIN	RVW 25th	RVW MED	RVW 75th	RVW MAX	Total Time	PRE-TIME EVAL	PRE-TIME POSIT	PRE-TIME SDW	INTRA-TIME MIN	INTRA-TIME 25th	INTRA-TIME MED	INTRA-TIME 75th	INTRA-TIME MAX	IMMD POST	FAC-inpt/same day 91	92	33	32	31	38	39	FAC-obs 26	25	24	17	Office 15	14	13	12	11	Prolonged 54	55	56	57
REF	63650	Percutaneous implantation of neurostimulator electrode array, epidural		0.0681			7.15			170	33	10	5			60			20						0.05							1							
CURRENT	64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed		0.056			7.15			187	45					70			30						0.05						1								
SVY	64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed		0.086	5.00	6.88	7.15	7.93	17.80	170	45	10	10	20	30	45	60	90	20												1								
REC	64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed		0.065			5.44			131	22	5	0			45			19												1								

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:

64561 Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed

Global Period: 010 Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee: RUC Advisors from each specialty society involved in this survey process reviewed the practice expense recommendations and approved them.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: These code are being reviewed so we are using 64561 as our reference code.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Visit prior to procedure:
Provide pre-service education and obtain consent from patient

Day of Procedure – Pre-Service
Greet the patient
Provide gown
Obtain urine specimen
Ensure appropriate medical records are available
Obtain three vitals (BP, weight and temperature)
Prepare room, equipment and supplies
Assist physician in positioning patient
Tray set up: (using sterile technique)

1. Tray draped with sterile drape
2. Necessary instruments arranged on tray
3. Solution for numbing drawn up

Betadine prep to sacral area, sterile drape placement and grounding pad placement confirmed.
Patient cable attached to external test stimulation box done.
C-arm positioned

Intra-Service Clinical Labor Activities:

Assist physician during the procedure
Hands necessary supplies and equipment to the physician

Post-Service Clinical Labor Activities:

Clean the room and equipment
Provide follow up information to patient.
Patient education/teaching as appropriate based upon the visit
Confers with the MD verbally for any last minute instructions for patient.
Next appointment is set up for patient while checking out.

Next day after patient leaves the office, clinical staff calls patient to verify system is working.

	A	B	C	D	E	F	G
1				EXISTING INPUTS			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**CPT Code # 64561**		**CPT Code # 64561**	
3	**Meeting Date: January 2014 Tab: 25 Specialty: American Urological Association, American Congress of Obstetricians and Gynecologists**	**CMS Code**	**Staff Type**	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed		Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed	
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**	**L037D**	**RN/LPN/MTA**	**010**	**010**	**010**	**010**
6	**TOTAL CLINICAL LABOR TIME**			**159.0**	**82.0**	**121.0**	**56.0**
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**18.0**	**23.0**	**0.0**	**0.0**
8	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**88.0**	**6.0**	**65.0**	**0.0**
9	**TOTAL POST-SERV CLINICAL LABOR TIME**			**53.0**	**53.0**	**56.0**	**56.0**
10	**PRE-SERVICE**						
11	**Start: Following visit when decision for surgery or procedure made**						
12	Complete pre-service diagnostic & referral forms			**5**	**5**		
13	Coordinate pre-surgery services			**3**	**3**		
14	Schedule space and equipment in facility				**5**		
15	Provide pre-service education/obtain consent			**7**	**7**		
16	Follow-up phone calls & prescriptions			**3**	**3**		
17	*Other Clinical Activity - *specify:*						
18	**End: When patient enters office/facility for surgery/procedure**						
19	**SERVICE PERIOD**						
20	**Start: When patient enters office/facility for surgery/procedure:**						
21	Greet patient, provide gowning, ensure appropriate medical records are available			**5**		**3**	
22	Obtain vital signs			**2**		**3**	
23	Provide pre-service education/obtain consent					**3**	
24	Prepare room, equipment, supplies			**2**		**2**	
25	Prepare and position patient/ monitor patient/ set up IV			**3**		**2**	
26	Sedate/apply anesthesia					**2**	
27	**Intra-service**						
28	Assist physician in performing procedure			**70**		**45**	
29	Assist physician/moderate sedation (100% of physician time)						
30	**Post-Service**						
31	Clean room/equipment by physician staff			**3**		**3**	
32	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions			**3**		**2**	
33	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)			**n/a**	**6**	**n/a**	
34	Dischrg mgmt (1.0 x 99238) (enter 12 min)			**n/a**		**n/a**	
35	Dischrg mgmt (1.0 x 99239) (enter 15 min)			**n/a**		**n/a**	
36	**End: Patient leaves office**						
37	**POST-SERVICE Period**						
38	**Start: Patient leaves office/facility**						
39	Conduct phone calls/call in prescriptions					**3**	**3**
40	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**
41	99211 16 minutes		16				
42	99212 27 minutes		27				
43	99213 36 minutes		36				
44	99214 53 minutes		53	**1**	**1**	**1**	**1**
45	99215 63 minutes		63				
46	**Total Office Visit Time**			**53.0**	**53.0**	**53.0**	**53.0**
47	*Other Clinical Activity - *specify:*						
48	**End: with last office visit before end of global period**						
49	**MEDICAL SUPPLIES****	**CODE**	**UNIT**				
50	pack, minimum multi-specialty visit	SA048	pack	**2**		**2**	**1**
51	**kit, percutaneous neuro test stimulation**	**SA022**	item	**1**		**1**	
52	pack, post-op incision care (suture)	SA054	item	**1**			
53	drape, sterile, c-arm, fluoro	SB008	item	**1**		**1**	
54	drape, sterile, for Mayo stand	SB012	item			**0**	
55	povidone swabsticks	SJ043	item			**0**	
56	steri-strip	SG074	item			**0**	
57	lidocaine 1%-2% inj (Xylocaine)	SH047	ml			**40**	
58	**EQUIPMENT**	**CODE**					
59	light, exam	EQ168		**141**		**118.0**	**53**
60	fluoroscopic system, mobile C-arm	ER031		**78**		**47**	
61	table, power	EF031				**118.0**	**53**
62	table, instrument, mobile	EF027				**47**	
63	table, exam	EF023		**141**			
64	percutaneous neuro test stimulator	EQ202				**65**	

AMA/Specialty Society RVS Update Committee Summary of Recommendations
CMS-Other - Utilization over 250,000 screen

January 2014

X-Ray Exams

The Relativity Assessment Workgroup identified these services through the CMS/Other Source – Utilization over 250,000 screen. In October 2013, the RUC noted that these services were never RUC reviewed but are frequently reported. The RUC recommended that these services be surveyed for physician work and develop direct practice expense inputs for the January 2014 RUC meeting. The specialty society presented a crosswalk methodology to validate the existing values for these plain film codes. The RUC did not accept the crosswalk methodology and requested action of the specialty societies by the September 2014 RUC meeting, acknowledging that the specialty societies may again pursue an alternative methodology through the Research Subcommittee. The Research Subcommittee considered the request during their March 4, 2014 meeting and determined that these services should be surveyed because they have not been recently reviewed. **The RUC recommends that these services be surveyed for physician work and develop direct practice expense inputs for the September 2015 RUC meeting.**

CPT Code (•New)	CPT Descriptor	Global Period	Work RVU Recommendation
71100	Radiologic examination, ribs, unilateral; 2 views	XXX	Postponed to September RUC meeting
72070	Radiologic examination, spine; thoracic, 2 views	XXX	Postponed to September RUC meeting
73060	Radiologic examination; humerus, minimum of 2 views	XXX	Postponed to September RUC meeting

73565	Radiologic examination, knee; both knees, standing, anteroposterior	XXX	Postponed to September RUC meeting
73590	Radiologic examination; tibia and fibula, 2 views	XXX	Postponed to September RUC meeting
73600	Radiologic examination, ankle; 2 views	XXX	Postponed to September RUC meeting

AMA/Specialty Society RVS Update Committee Summary of Recommendations
CMS Fastest Growing / MPC List screen

January 2014

CT Angiography-Chest

In October 2008, CPT code 71275 *Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing* was identified through the CMS Fastest Growing screen and later the MPC List screen. The RUC reviewed Medicare utilization in September 2011 and at the October 2013 meeting determined that this service should be surveyed for physician work and practice expense for review at the January 2014 RUC meeting.

The RUC reviewed the survey results from 89 physicians for CPT code 71275. The societies indicated, and the RUC agreed, that 5 minutes of pre-service time, 25 minutes of intra-service time and 5 minutes of post-service time, adequately account for the physician time required to perform this service. Based on these surveyed times, the RUC determined that a work RVU of 1.90, the survey 25th percentile, was not appropriate for this service. The RUC noted that the physician time significantly decreased from the survey that was presented to the RUC in February 2001. In order to maintain relatively across the family of computed tomography codes the RUC compared 71275 to recently reviewed CPT code 74177 *Computed tomography, abdomen and pelvis; with contrast material(s)* (work RVU=1.82). The RUC determined that a direct crosswalk to 74177, with identical pre, intra, and post time, accounts for the physician work and time associated with the surveyed code.

To further support this value, the RUC reviewed CPT code 92004 *Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program; comprehensive, new patient, 1 or more visits* (work RVU= 1.82) and determined that physician work and intensity are similar. Additionally the RUC noted that CPT code 74175 *Computed tomographic angiography, abdomen, with contrast material(s), including noncontrast images, if performed, and image postprocessing* with identical pre, intra and post time was reviewed at the October 2013 RUC meeting and the RUC approved a value of 1.82. **The RUC recommends a work RVU of 1.82 for CPT code 71275.**

Practice Expense
The RUC reviewed and approved the direct practice expense inputs with minor modifications as approved by the Practice Expense Subcommittee.

Work Neutrality
The RUC's recommendation for this code will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

CPT Code (•New)	CPT Descriptor	Global Period	Work RVU Recommendation
71275	Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing	XXX	1.82

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:71275 Tracking Number Original Specialty Recommended RVU: **1.90**
Presented Recommended RVU: **1.90**
Global Period: XXX RUC Recommended RVU: **1.82**

CPT Descriptor: Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: 65 year old male with history of hypertension complains of acute chest pain radiating to his neck and back. He is referred for a CTA of the chest to evaluate for an aortic dissection.

Percentage of Survey Respondents who found Vignette to be Typical: 92%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 2%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 1%

Description of Pre-Service Work:
• Review the reason for the exam and any pertinent clinical history including history of contrast allergy, renal insufficiency, or other contraindication to IV contrast.
• Review any prior imaging studies.
• Determine the appropriate CT protocol for the examination, confirm whether pre- and post-contrast images are indicated, and communicate that protocol to the CT technologists.

Description of Intra-Service Work:
• Supervise insertion of IV catheter, selection of contrast media, and set-up of mechanical injector.
• Obtain/interpret scout views of area to be imaged.
• Obtain/review non-contrast CT images to ensure proper anatomic coverage prior to contrast administration.
• Supervise low- or iso-osmolar contrast injection.
• Obtain the arterial phase CT images and review to ensure adequate anatomic coverage.
• Assess the need for additional delayed images based on the initial contrast phases (e.g. solid organ or complex vascular lesions, filling defects in the heart, as well as endoleak after stent graft repair of aneurysms).
• Create and/or supervise two-dimensional reconstructions of the vasculature and associated organs, interpret, and annotate.
• Supervise and/or create three-dimensional reconstructions of the vasculature and associated organs.
• Adjust the projection of the three-dimensional reconstructions to optimize visualization of anatomy or pathology and store the obtained images.
• Interpret the axial source images of the pre-contrast sequence, arterial phase sequence, and any additional delayed sequences, as well as the two-dimensional and three-dimensional reformatted images resulting from the study, often including cine review.

- Perform and record appropriate measurements for pre-operative assessment of vascular disease.
- Compare to all pertinent available prior studies.
- Dictate report.
- Document radiation exposure, specifically dose and/or registry reporting.

Description of Post-Service Work:

- Review, edit, and sign the final report.
- Communicate results to referring provider.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014				
Presenter(s):	Zeke Silva, MD; Kurt Schoppe, MD; Gerald Niedzwiecki, MD, Michael Hall, MD				
Specialty(s):	American College of Radiology, Society of Interventional Radiology				
CPT Code:	71275				
Sample Size:	986	**Resp N:**	89	**Response:** 9.0 %	
Description of Sample:	Random Sample				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	5.00	50.00	**100.00**	200.00	5000.00
Survey RVW:	1.40	1.90	**2.10**	2.30	3.50
Pre-Service Evaluation Time:			**5.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	1.00	15.00	**25.00**	30.00	50.00

Immediate Post Service-Time:	**5.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

XXX Global Code

CPT Code:	71275	**Recommended Physician Work RVU: 1.82**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**5.00**	**0.00**	**5.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**25.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

XXX Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**5.00**	**0.00**	**5.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
74178	XXX	2.01	**RUC Time**

CPT Descriptor Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
74176	XXX	1.74	**RUC Time**	1,974,195

CPT Descriptor 1 Computed tomography, abdomen and pelvis; without contrast material

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
74178	XXX	2.01	**RUC Time**	620,773

CPT Descriptor 2 Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions

Other Reference CPT Code	Global	Work RVU	Time Source

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 40 **% of respondents:** 44.9 **%**

TIME ESTIMATES (Median)	**CPT Code: 71275**	**Key Reference CPT Code:** 74178	**Source of Time** **RUC Time**

Median Pre-Service Time	5.00	5.00
Median Intra-Service Time	25.00	30.00
Median Immediate Post-service Time	5.00	5.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**35.00**	**40.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.83	3.60
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.93	3.38
Urgency of medical decision making	4.43	3.33
Technical Skill/Physical Effort (Mean)		
Technical skill required	3.98	3.48
Physical effort required	3.68	3.13
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	3.95	3.30
Outcome depends on the skill and judgment of physician	4.23	3.73
Estimated risk of malpractice suit with poor outcome	4.28	3.50

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	3.35	2.83
Intra-Service intensity/complexity	4.05	3.38
Post-Service intensity/complexity	3.45	2.88

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

Background

CPT code 71275 (*Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing*) was initially identified by the CMS Fastest Growing screen and later was also included in the MPC List screen. Utilization was monitored through September 2011 and at the October 2013 meeting this service was recommend for survey of both physician work and practice expense.

This code describes the use of CT angiography for evaluation of the intra-thoracic arteries (both the aorta and pulmonary arteries), surveillance of chronic vascular disease, as well as both surgical planning and follow-up.

Survey Process

The American College of Radiology and Society of Interventional Radiology surveyed this code, and convened an expert panel of physicians familiar with this service to review the survey data.

Work RVU

The expert panel recommends a work RVU of 1.90, which is the 25th percentile survey value and below the current value of 1.92.

Service Times

The panel recommends the median survey times for 71275 of 5 minutes pre, 25 minutes intra, and 5 minutes post.

The median pre- and post-service survey times of 5 minutes each for 71275 are the same as the key reference service (74178) and are less than the current pre and post times of 9.5 and 10 minutes, respectively.

Key Reference Service

Our recommendations compare favorably to the most commonly selected key reference service 74178 *(Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions)*, which was chosen by 45% of those surveyed. 74178 also resides on the MPC list and has a higher work RVU of 2.01, the same pre and post service times as the recommended values for 71275, and a slightly longer intra-service time of 30 minutes. Additionally, 71275 was rated higher than 74178 on all 11 complexity measurements, supporting the higher IWPUT of 0.067.

Code	RVU	Pre	Intra	Post	Total	IWPUT	RUC Date
71275	1.90	5	25	5	35	0.067	Jan 14
74178	2.01	5	30	5	40	0.060	Feb 10

MPC Comparison

The expert panel recommendation of 1.90 RVUs for 71275 is bracketed by two codes on the MPC list, 74176 and the key reference service, 74178:

74176 *(Computed Tomography, abdomen and pelvis; without contrast material), and*
74178 *(Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions).*

Code	RVU	Pre	Intra	Post	Total	IWPUT	RUC Date	Global
74176	1.74	5	22	5	32	0.069	Feb 10	XXX
71275	1.90	5	25	5	35	0.067	Jan 14	XXX
74178	2.01	5	30	5	40	0.060	Feb 10	XXX

Conclusion
Our recommendations for 71275 represent a decrease in work RVU relative to the current value, as well as small decreases in the pre, intra, and post service times. Even though we are not pursuing compelling evidence to support the median survey value, it is important to note that both KRS and MPC comparisons each provide strong support for an increase in value for 71275. Additionally, the current recommendation for Chest CTA (71275) maintains relativity with the October 2013 surveyed and RUC approved visceral CTA codes (72191, 74174, 74175) as shown in the table below.

Code	RVU	Pre	Intra	Post	Total	IWPUT	RUC Date	Global
72191	1.81	5	25	5	35	0.063	Oct 13	XXX
74175	1.82	5	25	5	35	0.064	Oct 13	XXX
71275	1.90	5	25	5	35	0.067	Jan 14	XXX
74174	2.20	5	30	5	40	0.066	Oct 13	XXX

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 71275

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Diagnostic Radiology How often? Commonly

Specialty Interventional Radiology How often? Sometimes

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 2213520
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. The overall number of services described by 71275 provided nationally in a one-year period is estimated to be 2,213,520.

Specialty Diagnostic Radiology Frequency 2114140 Percentage 95.51 %

Specialty Interventional Radiology Frequency 40391 Percentage 1.82 %

Specialty Frequency 0 Percentage 0.00 %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 737,840 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. The 2013 Medicare data estimates that CPT code 71275 was billed approximately 737,840 times for Medicare patients nationally in a one-year period

Specialty Diagnostic Radiology Frequency 704750 Percentage 95.51 %

Specialty Interventional Radiology Frequency 13463 Percentage 1.82 %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Imaging

BETOS Sub-classification:
Advanced imaging

BETOS Sub-classification Level II:
CAT/CT/CTA: Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 71275

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

SS Rec Summary

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	AO	AP	AQ	AR	AS
12	**ISSUE:** CTA																								
13	**TAB:** 27																								
14						RVW					Total	PRE-TIME			INTRA-TIME					IMMD	SURVEY EXPERIENCE				
15	Source	CPT	DESC	Resp	IWPUT	MIN	25th	MED	75th	MAX	Time	EVAL	POSIT	SDW	MIN	25th	MED	75th	MAX	POST	MIN	25th	MED	75th	MAX
16	REF - Feb '10	74178	Computed ton	40	0.060			2.01			40	5					30			5					
17	RUC - Feb '01	71275	Computed tomograp		0.049			1.92			49.5	9.5					30			10					
18	SVY	71275	Computed ton	89	0.075	1.40	1.90	2.10	2.30	3.50	35	5			1	15	25	30	50	5	5	50	100	200	5000
19	REC	71275	Computed tomograp		0.06384			1.82			35	5					25			5					

CPT Code: 71275
Specialty Society('s) ACR, SIR

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:

71275	Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image

Global Period: XXX Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

The American College of Radiology and the Society of Interventional Radiology convened a consensus panel to finalize the practice expense data for CPT code 71275.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale:

Since 71275 is an existing code, we used the inputs from the CMS refinement of the inputs which were approved by the Practice Expense Advisory Committee and the full RUC in 2001 as the basis for the practice expense inputs. CPT code 74175 *(Computed tomographic angiography, abdomen)* was recently reviewed and approved at the October 2013 RUC meeting, and is included as areference to demonstrate consistency across the CTA family

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:

- **Prepare and position patient/ monitor patient/ set up IV -** We are recommending 5 minutes. This extra time is necessary to ensure appropriate positioning of the patient for several reasons: (1) patient comfort to minimize the possibility of motion artifact; (2) to ensure that the entire chest will remain in the field of view and (3) to ensure that the arms and other objects do not lead to artifacts such as beam hardening or quantum mottle; (4) to ensure appropriate positioning of the injector and support devices relative to the patient and (5) to ensure an adequate view of the IV site by the technologist to evaluate for extravasation during power injection.

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:

Supplies

- **Tubing, sterile, connecting (fluid administration) (SD212)** – clinically necessary for CTA examinations.
- **Computer media, dvd (SK013) -** clinically necessary for CTA examinations.
- **Film, x-ray, laser print (SK098)** – clinically necessary for CTA examinations.
- **X-ray developer solution (SK089) -** clinically necessary for CTA examinations.

- **X-ray fixer solution (SK092) -** clinically necessary for CTA examinations.
- **Sodium chloride 0.9% inj (250-1000ml uou) (SH067) -** clinically necessary for CTA examinations.
- **Paper, exam table (SB036) -** clinically necessary for CTA examinations.
- **Tape, elastic, 1in (Elastoplast, Elasticon) (5yd uou) (SG075) -** clinically necessary for CTA examinations.
- **Syringe, 25ml (MRI power injector) (SC059) -** clinically necessary for CTA examinations.

Equipment

- **Computer workstation, 3D reconstruction CT-MR (ED014) –** Clinically necessary equipment. for 3-D post processing. 33 minutes was approved at the October 2013 RUC for the visceral CTA family.
- **Film alternator (motorized film viewbox) (ER029) –** Clinically necessary. 15 minutes was approved at the October 2013 RUC for the visceral CTA family.
- **Printer, laser, paper (ED032) –** Clinically necessary. 10 minutes was approved at the October 2013 RUC for the visceral CTA family.

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

- Availability of prior images confirmed
- Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist

Intra-Service Clinical Labor Activities:

- Greet patient, provide gowning, ensure appropriate medical records are available
- Provide pre-service education/obtain consent
- Prepare room, equipment, supplies
- Prepare and position patient/ monitor patient/ set up IV
- Acquire images
- Assist physician in performing procedure/Computer post processing
- Clean room/equipment by physician staff
- Technologist QC's images in PACS, checking for all images, reformats, and dose page
- Review examination with interpreting MD
- Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue

Post-Service Clinical Labor Activities:

	A	B	C	D	E	F
1	REVISED AT RUC 1/29/14			REFERENCE CODE	REFERENCE CODE	
2	*Please note: If a supply has a purchase price of $100 or			74175	71275	71275
3	Meeting Date: January 2014 Tab: 27 Specialty: ACR, SIR	CMS Code	Staff Type	Computed tomographic angiography, abdomen, with contrast material(s), including noncontrast images, if performed, and image postprocessing RUC Oct 2013	Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing CMS Refinement	Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing RUC Jan 2014
4	LOCATION			Non Fac	Non Fac	Non Fac
5	GLOBAL PERIOD			XXX	XXX	XXX
6	TOTAL CLINICAL LABOR TIME	L046A	CT Tech	75.0	0.0	79.0
7		L041B	Rad Tech	10.0	122.0	6.0
8	TOTAL PRE-SERV CLINICAL LABOR TIME	L046A	CT Tech	0.0	0.0	4.0
9		L041B	Rad Tech	4.0	5.0	0.0
10	TOTAL SERVICE PERIOD CLINICAL LABOR TIME	L046A	CT Tech	75.0	0.0	75.0
11		L041B	Rad Tech	6.0	112.0	6.0
12	TOTAL POST-SERV CLINICAL LABOR TIME	L046A	CT Tech	0.0	0.0	0.0
13		L041B	Rad Tech	0.0	5.0	0.0
14	PRE-SERVICE					
15	Start: Following visit when decision for surgery or procedure made					
16	Complete pre-service diagnostic & referral forms					
17	Coordinate pre-surgery services					
18	Schedule space and equipment in facility					
19	Provide pre-service education/obtain consent					
20	Follow-up phone calls & prescriptions					
21	Availability of prior images confirmed	L041B	CT Tech	2	5 (RT)	2
22	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	L041B	CT Tech	2		2
23	*Other Clinical Activity - *specify:*					
24	End: When patient enters office/facility for surgery/procedure					
25	SERVICE PERIOD					
26	Start: When patient enters office/facility for surgery/procedure:					
27	Greet patient, provide gowning, ensure appropriate medical records are available	L041B	Rad Tech	3	3	3
28	Obtain vital signs					
29	Provide pre-service education/obtain consent	L046A	CT Tech	2	2 (RT)	2
30	Prepare room, equipment, supplies	L046A	CT Tech	2	5 (RT)	2
31	Setup scope (non facility setting only)					
32	Prepare and position patient/ monitor patient/ set up IV	L046A	CT Tech	5	7 (RT)	5
33	Sedate/apply anesthesia					
34	*Other Clinical Activity - specify:					
35	Intra-service					
36	Acquire images	L046A	CT Tech	28	28 (RT)	28
37	*Starting IV for high volume and rate power injection*	L046A	CT Tech		5 (RT)	
38	~~*Assist physician in performing procedure/*~~ *Computer post processing*	L046A	CT Tech	33	57 (RT)	33
39	Post-Service					
40	Monitor pt. following moderate sedation					
41	Monitor pt. following service/check tubes, monitors, drains not related to moderate sedation					
42	Clean room/equipment by physician staff	L041B	Rad Tech	3	5	3
43	Clean Scope					
44	Clean Surgical Instrument Package					
45	Complete diagnostic forms, lab & X-ray requisitions					
46	Review/read X-ray, lab, and pathology reports					
47	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions					
48	*Other Clinical Activity - *specify:*					
49	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)			n/a	n/a	n/a
50	Dischrg mgmt (1.0 x 99238) (enter 12 min)			n/a	n/a	n/a
51	Dischrg mgmt (1.0 x 99239) (enter 15 min)			n/a	n/a	n/a
52	*Other Clinical Activity - *specify:*					
53	*Review films with physican for adequacy*	L041B	Rad Tech		5	
54	Technologist QC's images in PACS, checking for all images, reformats, and dose page	L046A	CT Tech	2		2
55	Review examination with interpreting MD	L046A	CT Tech	2		2
56	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	L046A	CT Tech	1		1
57	End: Patient leaves office					
58	POST-SERVICE Period					
69	MEDICAL SUPPLIES**	CODE	UNIT			
70	syringe, pressure (radiology)	SC060	item	1	1	1
71	film, x-ray 14in x 17in	SK034	item	8	24	8
72	x-ray envelope	SK091	item		1	
73	gloves, sterile	SB024	pair		1	
74	gown, patient	SB026	item	1	1	1
75	stop cock, 4-way	SC050	item	1	1	1
76	tape, surgical paper 1in (Micropore)	SG079	inch	6	6	6
77	tubing, sterile, connecting (fluid administration)	SD212	feet	1		1
78	iv tubing (extension)	SC019	foot	3		3
79	computer media, dvd	SK013	item	1		1
80	film, x-ray, laser print	SK098	item	11		11
81	x-ray developer solution	SK089	oz	8		8
82	x-ray fixer solution	SK092	oz	8		8
83	sodium chloride 0.9% inj (250-1000ml uou)	SH067	item	1		1
84	paper, exam table	SB036	foot	7		7
85	tape, elastic, 1in (Elastoplast, Elasticon) (5yd uou)	SG075	item	0		0
86	syringe, 25ml (MRI power injector)	SC059	item	1		1
87	Imaging with Contrast Package	new	item	1		1
88	bandage, strip 0.75in x 3in (Bandaid)	SG021	item		1	
89	angiocatheter 14g-24g	SC001	item		1	
90	iv tubing (extension)	SC019	foot		1	
91	needle, 18-27g	SC029	item		1	
92	sodium chloride 0.9% inj bacteriostatic (30ml uou)	SH068	item		0.34	
93	swab-pad, alcohol	SJ053	item		1	
94	EQUIPMENT					
95	room, CT	EL007		40	55	40
96	film processor, dry, laser	ED024		15	10	15
97	computer workstation, 3D reconstruction CT-MR	ED014		33		33
98	film alternator (motorized film viewbox)	ER029		15		15
99	printer, laser, paper	ED032		10		10

AMA/Specialty Society RVS Update Committee Summary of Recommendations
CMS-Other - Utilization over 250,000

January 2014

Swallowing Function

The RUC identified CPT code 74230 through the CMS/Other Source – Utilization over 250,000 screen. In October 2013, the RUC noted that this service was never RUC reviewed but is frequently reported. The RUC recommended that these services be surveyed for physician work and develop direct practice expense inputs for the January 2014 RUC meeting.

The RUC reviewed the survey results from 60 radiologists and neuroradiologtists for CPT code 74230 *Swallowing function, with cineradiography/videoradiography* and determined that the current work RVU of 0.53 should be maintained. The RUC recommends 3 minutes pre-service time, 10 minutes intra-service time and 4 minutes immediate post-service time. A RUC member questioned how often the radiologist reviews the video recording, in which the specialty societies indicated that the radiologists typically reviews a portion of the video in specific instances to review when there laryngeal penetration, aspiration or pooling of ingested material occurred. However, the radiologist does not typically review the entire video recording. The RUC compared 74230 to the key reference service 74247 *Radiological examination, gastrointestinal tract, upper, air contrast, with specific high density barium, effervescent agent, with or without glucagon; with or without delayed films, with KUB* (work RVU = 0.69) and determined that the surveyed service requires less physician work and 5 minutes less intra-service time to complete and therefore appropriately valued the surveyed code lower. For additional support, the RUC referenced MPC code 76536 *Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation* (work RVU = 0.56), which requires similar physician work and both require 10 minutes of intra-service time and therefore should be valued similarly. **The RUC recommends a work RVU of 0.53 for CPT code 74230.**

Practice Expense
The RUC recommends the direct practice inputs as reviewed by the Practice Expense Subcommittee with no modifications.

CPT Code (●New)	CPT Descriptor	Global Period	Work RVU Recommendation
74230	Swallowing function, with cineradiography/videoradiography	XXX	0.53 (No Change)

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:74230 Tracking Number Original Specialty Recommended RVU: **0.53**
Presented Recommended RVU: **0.53**
Global Period: XXX RUC Recommended RVU: **0.53**

CPT Descriptor: Swallowing function, with cineradiography/videoradiography

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: 85 year old male patient with history of cerebral infarction presents with recurrent pneumonia. Swallowing function study requested to evaluate for aspiration.

Percentage of Survey Respondents who found Vignette to be Typical: 92%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 2%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 2%

Description of Pre-Service Work:
• Review the request for appropriateness and review clinical history.
• Review any prior applicable studies.
• Confirm protocol with speech pathologist.

Description of Intra-Service Work:
• Obtain scout fluoroscopic image of neck in AP and lateral views prior to administration of oral substances.
• Observe patient under fluoroscopy swallow thin liquids, thick liquids, nectar thick liquids, soft solids, and hard solids in lateral position (AP position when needed).
• May need additional fluoroscopic observation while patient swallows solids followed by liquid wash, or observe patient swallow liquids with chin tuck positioning.
• Observe fluoroscopic real time and fluoroscopic video recordings evaluating: 1) Oral Phase (moistening, mastication, trough formation, movement of bolus posteriorly). 2) Pharyngeal Phase (closure of nasopharynx, oropharynx preparation to receive bolus, closure of larynx, hyoid elevation, bolus transit to pharynx). 3) Esophageal Phase (esophageal peristalsis, pharyngeal/laryngeal relaxation).
• Assess for poor airway coverage (epiglottis dysfunction), penetration, aspiration, reflux, Zenker's/Killian Jamieson diverticula, cricopharyngeal achalasia, filling defects suggesting mass or retained foreign bodies, external compression (large thyroid, retropharyngeal carotid artery, large cervical osteophytes).

Description of Post-Service Work:
• Dictate report.
• Review and sign final report.
• Communicate findings with referring physician and/or patient/patient's family.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014		
Presenter(s):	Zeke Silva, MD; Kurt Schoppe, MD; Joshua Hirsch, MD; Greg Nicola, MD		
Specialty(s):	American College of Radiology, American Society of Neuroradiology		
CPT Code:	74230		
Sample Size:	1953	**Resp N:** 60	**Response:** 3.0 %
Description of Sample:	Random Sample		

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	20.00	**50.00**	100.00	600.00
Survey RVW:	0.30	0.55	**0.63**	0.78	3.00
Pre-Service Evaluation Time:			**3.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	5.00	10.00	**10.00**	15.00	90.00

Immediate Post Service-Time:	**4.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

XXX Global Code

CPT Code:	74230	**Recommended Physician Work RVU: 0.53**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**3.00**	**0.00**	**3.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**10.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

XXX Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**4.00**	**0.00**	**4.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
74247	XXX	0.69	**RUC Time**

CPT Descriptor Radiological examination, gastrointestinal tract, upper, air contrast, with specific high density barium, effervescent agent, with or without glucagon; with or without delayed films, with KUB

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
76536	XXX	0.56	**RUC Time**	694,976

CPT Descriptor 1 Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization

CPT Descriptor 2

Other Reference CPT Code	Global	Work RVU	Time Source

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 45 **% of respondents:** 75.0 **%**

TIME ESTIMATES (Median)	**CPT Code: 74230**	**Key Reference CPT Code:** 74247	**Source of Time** **RUC Time**

Median Pre-Service Time	3.00	5.00
Median Intra-Service Time	10.00	15.00
Median Immediate Post-service Time	4.00	5.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**17.00**	**25.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	2.67	3.16
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	2.31	2.71
Urgency of medical decision making	2.38	2.51
Technical Skill/Physical Effort (Mean)		
Technical skill required	2.40	3.09
Physical effort required	2.13	2.64
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	1.84	1.84
Outcome depends on the skill and judgment of physician	2.93	3.29
Estimated risk of malpractice suit with poor outcome	1.84	2.20

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	1.60	1.82
Intra-Service intensity/complexity	3.16	3.40
Post-Service intensity/complexity	2.02	2.27

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

Background

CPT Code 74230 describes the work required by a physician to evaluate a patient's swallowing function under cineradiography/videoradiography. 74230 was identified on the April 2013 Relativity Assessment Workgroup screen for CMS/Other source codes with Medicare utilization over 250,000 or more.

Videoradiography/cineradiography is a valuable tool used when a physician wants to evaluate the swallowing function of a patient who has risk factors for aspiration or documented aspiration events. These patients typically have either an anatomic cause (such as prior head and neck surgery or radiation) or a neurologic cause (stroke, brain trauma) which has compromised the normal complex series of events required for a patient to swallow safely and effectively. This procedure can be performed with a consulting speech pathology specialist who would use a different set of CPT codes.

The American College of Radiology (ACR) and American Society of Neuroradiology (ASNR) surveyed 74230, and convened an expert panel of physicians familiar with the services to review the survey data.

Work RVU Recommendations

The expert panel recommends maintaining current wRVU of 0.53 for 74230, which is less than the 25th percentile of our survey.

Pre, Intra, and Post Service Times

The panel is recommending the survey median times of 3 minutes of pre-service time, 10 minutes of intra-service time, and 4 minutes of post service time for a total time of 17 minutes.

CPT Code	Short Descriptor	Work RVU	Pre-Service	Intra-Service	Post-Service	Total Time	IWPUT
74230	Swallow function cine or videoradiography	0.53	3	10	4	17	0.0370

KRS for 74230

The key reference for 74230 is 74247, chosen by 75% of our survey respondents. The work RVU difference between 74230 and the KRS, 74247, is proportionate to the intra-service time and total time differences.

CPT Code	Short Descriptor	Work RVU	Pre-Service	Intra-Service	Post-Service	Total Time	IWPUT
74230	Swallow function cine or videoradiography	0.53	3	10	4	17	0.0370
74247	Contrast x-ray uppr GI tract	0.69	5	15	5	25	0.0311

MPC for 74230

Our recommendation is compared to MPC code 76536 [Ultrasound soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation)]. These two codes are nearly identical in times except for a 1 minute difference in pre-service time favoring the MPC. This difference is balanced by an equivalent reduction in wRVU for 74230.

CPT Code	Short Descriptor	Work RVU	Pre-Service	Intra-Service	Post-Service	Total Time	IWPUT
74230	Swallow function cine or videoradiography	0.53	3	10	4	17	0.0370
76536	US exam head and neck	0.56	4	10	4	18	0.0381

Summary:

In summary, our expert panel recommends maintaining the current value of 74230 at 0.53 wRVU with median service period times of 3, 10, and 4 minutes. We believe this compares favorably with the key reference service, 74247, and MPC code, 76536.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 74230

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Diagnostic Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 1170375
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. The overall number of services described by 74230 provided nationally in a one-year period is estimated to be 1170375.

Specialty Diagnostic Radiology Frequency 1046400 Percentage 89.40 %

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 390,125 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. The 2013 Medicare data estimates that CPT code 74230 was billed approximately 390,125 times for Medicare patients nationally in a one-year period

Specialty Diagnostic Radiology Frequency 348800 Percentage 89.40 %

Specialty Frequency Percentage %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Imaging

BETOS Sub-classification:
Standard imaging

BETOS Sub-classification Level II:
Contrast Gastrointestinal

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 74230

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

SS Rec Summary

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	AO	AP	AQ	AR	AS
12	**ISSUE:** Swallowing Function																								
13	**TAB:** 28																								
14						RVW					Total	PRE-TIME			INTRA-TIME					IMMD	SURVEY EXPERIENCE				
15	Source	CPT	DESC	Resp	IWPUT	MIN	25th	MED	75th	MAX	Time	EVAL	POSIT	SDW	MIN	25th	MED	75th	MAX	POST	MIN	25th	MED	75th	MAX
16	REF - Sept '11	74247	Radiological e	45	0.031			0.69			25	5					15			5					
17	CMS/Other	74230	Swallowing function		#DIV/0!			0.53			12														
18	SVY	74230	Swallowing fu	60	0.047	0.30	0.55	0.63	0.78	3.00	17	3			5	10	10	15	90	4	0	20	50	100	600
19	REC	74230	Swallowing function		0.037			0.53			17	3					10			4					

CPT Code: 74230
Specialty Society('s) ACR, ASNR

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:

74230	Swallowing function, with cineradiography/videoradiography

Global Period: XXX Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

The American College of Radiology and the American Society of Neuroradiology convened a consensus panel to finalize the practice expense data for CPT code 74230.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale:

Since 74230 is existing code, we used the inputs from the CMS refinement of the inputs which were approved by the PEAC and the full RUC in January 2004 as the basis for the practice expense inputs. CPT code 92611 is the code reported by the speech language pathologists for a comparable procedure, and is included as a reference.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:

- **Prepare and position patient/ monitor patient/ set up IV –** extra time required due to the complex nature of the patient, who is often debilitated and requires assistance.

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:

Supplies:

- **Barium suspension (Polibar) (SH016)** – 60 ml clinically necessary**.**
- **Barium high density susp (11-12oz uou) (SH013)** – 1 item clinically necessary.
- **Barium, honey (Varibar) (SH017)** – 60 ml clinically necessary.
- **Barium, nectar (Varibar) (SH018)** – 60 ml clinically necessary.
- **Barium, pudding (Varibar) (SH019)** – 60 ml clinically necessary.
- **Cookie (each) (SK017)** – 1 cookie clinically necessary.
- **Drinking straw (SK020)** – 1 straw clinically necessary.
- **Spoon, plastic (SK077)** – 2 spoons clinically necessary.
- **Tongue depressor (SJ061)** – 1 tongue depressor clinically necessary.

Equipment:

- **Chair with headrest, exam, reclining –** clinically necessary equipment for procedure.

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Intra-Service Clinical Labor Activities:

- Greet patient, provide gowning, ensure appropriate medical records are available
- Prepare room, equipment, supplies
- Prepare and position patient/ monitor patient/ set up IV
- Assist physician in performing fluoroscopy and spot film acquisition
- Clean room/equipment by physician staff
- Technologist QC's images in PACS, checking for all images, reformats, and dose page
- Review examination with interpreting MD
- Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue

Post-Service Clinical Labor Activities:

	A	B	C	D	E	F
1				REF CODE	REF CODE	
2	**more please bold the item name and CMS code.**			**92611**	**74230**	**74230**
3	**Meeting Date: January 2014** **Tab: 28** **Specialty: ACR, ASNR**	**CMS Code**	**Staff Type**	Motion fluoroscopic evaluation of swallowing function by cine or video recording RUC Feb 2009	Swallowing function, with cineradiography/videoradiography CMS Refinement	Swallowing function, with cineradiography/videoradiography RUC Jan 2014
4	**LOCATION**			**Non Fac**	**Non Fac**	**Non Fac**
5	**GLOBAL PERIOD**			**XXX**	**XXX**	**XXX**
6	**TOTAL CLINICAL LABOR TIME**	**L041B**	**Rad Tech**		**29.0**	**34.0**
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**	**L041B**	**Rad Tech**		**0.0**	**0.0**
8	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**	**L041B**	**Rad Tech**		**29.0**	**34.0**
9	**TOTAL POST-SERV CLINICAL LABOR TIME**	**L041B**	**Rad Tech**		**0.0**	**0.0**
10	**PRE-SERVICE**					
21	**SERVICE PERIOD**					
22	**Start: When patient enters office/facility for surgery/procedure:**					
23	Greet patient, provide gowning, ensure appropriate medical records are available	**L041B**	**Rad Tech**		**3**	**3**
24	Obtain vital signs					
25	Provide pre-service education/obtain consent					
26	Prepare room, equipment, supplies	**L041B**	**Rad Tech**		**2**	**2**
27	Setup scope (non facility setting only)					
28	Prepare and position patient/ monitor patient/ set up IV	**L041B**	**Rad Tech**		**1**	**6**
29	Sedate/apply anesthesia					
30	*Other Clinical Activity - specify:					
31	**Intra-service**					
32	Acquire images					
33	Assist physician in performing fluoroscopy and spot film acquisition	**L041B**	**Rad Tech**		**15**	**15**
34	**Post-Service**					
35	Monitor pt. following moderate sedation					
36	Monitor pt. following service/check tubes, monitors, drains not related to moderate sedation					
37	Clean room/equipment by physician staff	**L041B**	**Rad Tech**		**3**	**3**
38	Clean Scope					
39	Clean Surgical Instrument Package					
40	Complete diagnostic forms, lab & X-ray requisitions					
41	Review/read X-ray, lab, and pathology reports					
42	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions					
43	*Other Clinical Activity - *specify:*					
44	Process films, hang films and review study with interpreting MD prior to patient discharge	**L041B**	**Rad Tech**		**5**	
45	Technologist QC's images in PACS, checking for all images, reformats, and dose page	**L041B**	**Rad Tech**			**2**
46	Review examination with interpreting MD	**L041B**	**Rad Tech**			**2**
47	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	**L041B**	**Rad Tech**			**1**
48	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)				**n/a**	**n/a**
49	Dischrg mgmt (1.0 x 99238) (enter 12 min)				**n/a**	**n/a**
50	Dischrg mgmt (1.0 x 99239) (enter 15 min)				**n/a**	**n/a**
51	**End: Patient leaves office**					
52	**POST-SERVICE Period**					
64	**MEDICAL SUPPLIES****	**CODE**	**UNIT**			
65	gown, patient	SB026	item		**1**	**1**
66	barium suspension (Polibar)	SH016	ml		**1**	**60**
67	barium high density susp (11-12oz uou)	SH013	item			**1**
68	barium, honey (Varibar)	SH017	ml	**8**		**60**
69	barium, nectar (Varibar)	SH018	ml	**240**		**60**
70	barium, pudding (Varibar)	SH019	ml	**8**		**60**
71	cookie (each)	SK017	item	**1**		**1**
72	drinking straw	SK020	item	**1**		**1**
73	spoon, plastic	SK077	item	**2**		**2**
74	tongue depressor	SJ061	item	**1**		**1**
75	film, x-ray 10in x 12in	SK033	item		**4**	**4**
76	x-ray developer solution	SK089	oz		**4**	**4**
77	x-ray envelope	SK091	item		**1**	
78	x-ray fixer solution	SK092	oz		**4**	**4**
79	gloves, non-sterile	SB022	pair	**1**		
80	computer media, dvd	SK013	item	**1**		
81	**EQUIPMENT**	**CODE**				
82	room, radiographic-fluoroscopy	EL014			**29**	**28**
83	film alternator (motorized film)	ER029			**5**	**5**
84	film processor, wet	ED025			**5**	**5**
85	chair with headrest, exam, reclining	EF008		**35**		**28**

AMA/Specialty Society RVS Update Committee Summary of Recommendations
New Technology/New Services screen

January 2014

Microdissection

CPT code 88381 was identified through the New Technology/New Services List in February 2007. In October 2013, the Relativity Assessment Workgroup noted there may have been diffusion in technology for this service and requests that the specialty society's survey physician work and review practice expense at the January 2014 meeting. Code 88380 was added as part of this family.

88380 ***Microdissection (ie, sample preparation of microscopically identified target); laser capture***
The RUC reviewed the survey results from 31 pathologists and agreed with the specialty societies that 33 minutes of intra-service time, with 0 pre and post time is appropriate for this service. The RUC noted that while the survey median intra-service time indicated 28 minutes, there was 5 additional minutes in the pre-service component that is more accurately captured in the intra-service component. The specialty societies explained that pathologists must perform additional work prior to actually performing the microdissection. These include evaluating where the sample is located appropriate for the assay and ensuring this procedure will answer the appropriate clinical question being asked by the referring physician. For pathology services the RUC specifies intra-service time as anything the physician does from the time the laboratory receives the specimen until it is signed out. Therefore, the RUC agreed that it was appropriate to move the 5 minutes associated with this work to the intra-service time.

To value this procedure, the RUC noted that due to the decrease in intra-service time from the current time, 45 minutes, to the survey time, 33 minutes, a decrease in the current work RVU of 1.56 was appropriate. Therefore, the RUC agreed that the survey 25th percentile work RVU of 1.14 was appropriate for CPT code 88380. To justify this value, the RUC compared the surveyed code to CPT codes 88120 *Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual* (work RVU= 1.20, intra time= 30 minutes) and 88360 *Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, each antibody; manual* (work RVU= 1.10, intra time= 35 minutes) and agreed that these two pathology codes, with similar intra-service times and physician work, are appropriate validations for the recommended value for 88380. In addition, the RUC reviewed a service outside the pathology family and noted that CPT code 77334 *Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)* (work RVU= 1.24, intra time= 35) has slightly greater intra-service time compared to the surveyed code and is appropriately valued slightly higher. **The RUC recommends a work RVU of 1.14 for CPT code 88380.**

88381 ***Microdissection (ie, sample preparation of microscopically identified target); manual***
The RUC reviewed the survey results from 64 pathologists and agreed with the specialty societies that 20 minutes of intra-service time, with 0 pre and post time is appropriate for this service. The RUC noted that while the survey median intra-service time indicated 15 minutes, there was 5 additional minutes in the pre-service component that is more accurately captured in the intra-service component. The specialty societies explained that pathologists must perform additional work prior to actually performing the microdissection. These include evaluating where the sample is located appropriate for the assay and ensuring this procedure will answer the appropriate clinical question being asked by the referring physician. For pathology services the RUC specifies intra-service time as anything the physician does from the time the laboratory receives the specimen until it is signed out. Therefore, the RUC agreed that it was appropriate to move the 5 minutes associated with this work to the intra-service time.

To value this procedure, the RUC noted that due to the decrease in intra-service time from the current time, 30 minutes, to the survey time, 20 minutes, a decrease in the current work RVU of 1.18 was appropriate. Therefore, the RUC agreed that the survey 25th percentile work RVU of 0.53 was appropriate for CPT code 88381. To justify this value, the RUC compared the surveyed code to CPT codes 88172 *Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode, each site* (work RVU= 0.69, intra time= 20 minutes) and 88387 *Macroscopic examination, dissection, and preparation of tissue for non-microscopic analytical studies (eg, nucleic acid-based molecular studies); each tissue preparation (eg, a single lymph node)* (work RVU= 0.62, intra time= 20 minutes) and agreed that these two pathology codes, with identical intra-service time and physician work, are appropriate validations for the recommended value for 88381. **The RUC recommends a work RVU of 0.53 for CPT code 88381.**

Practice Expense:
The direct practice expense inputs were reviewed by the Practice Expense Subcommittee and several changes were made to the existing PE inputs. First, while the total times are not changing, much of the clinical labor work is moving from histotechnologists (L037B) to cytotechnologists (L045A). In addition, the number of microscope slides has risen from 2 to 11 and 9, respectively. This reflects the shift of molecular pathology using gene sequencing and requiring more slides. Finally, several pieces of equipment were added including a fume hood to reflect current clinical practice. The RUC accepted the direct practice expense inputs as modified by the PE Subcommittee.

Work Neutrality:
The RUC's recommendation for these codes will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

CPT Code (•New)	CPT Descriptor	Global Period	Work RVU Recommendation
88380	Microdissection (ie, sample preparation of microscopically identified target); laser capture	XXX	1.14
88381	Microdissection (ie, sample preparation of microscopically identified target); manual	XXX	0.53

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:88380 Tracking Number Original Specialty Recommended RVU: **1.14**
Presented Recommended RVU: **1.14**
Global Period: XXX RUC Recommended RVU: **1.14**

CPT Descriptor: Microdissection (ie, sample preparation of microscopically identified target); laser capture

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 67 year old female, undergoes fine needle aspiration biopsy of a mediastinal lymph node which demonstrates metastatic adenocarcinoma of the lung. Sections from the cell block are sent to the molecular laboratory for EGFR mutation testing.

Percentage of Survey Respondents who found Vignette to be Typical: 87%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting?
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting?
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: N/A

Description of Intra-Service Work: A review of a serial slides shows tiny clusters of cancer cells interspersed among numerous lymphocytes. The tumor and normal cells are almost inseparable All the blank slides are stained with a DNA compatible stain. The pathologist performs laser capture microdissection of multiple high power fields to be able to obtain an adequate number of cells for DNA sequencing. Typically over 2,000 cells are microdissected for each assay.

Description of Post-Service Work: N/A

SURVEY DATA

RUC Meeting Date (mm/yyyy)	02/2014				
Presenter(s):	Jonathan L. Myles, MD, Lee H. Hilborne, MD, Mahesh Mansukhani, MD				
Specialty(s):	College of American Pathologists and American Society of Clinical Pathology				
CPT Code:	88380				
Sample Size:	12861	**Resp N:**	31	**Response:** 0.2 %	
Description of Sample:	Random and Targeted				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	2.00	10.00	**30.00**	50.00	150.00
Survey RVW:	0.50	1.14	**1.35**	1.44	1.59
Pre-Service Evaluation Time:			**5.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	5.00	15.00	**28.00**	50.00	75.00

Immediate Post Service-Time:	**10.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

XXX Global Code

CPT Code:	88380	**Recommended Physician Work RVU: 1.14**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**0.00**	**0.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**33.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

XXX Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
88173	XXX	1.39	**RUC Time**

CPT Descriptor Cytopathology, evaluation of fine needle aspirate; interpretation and report

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
90935	000	1.48	**RUC Time**	1,343,209

CPT Descriptor 1 Hemodialysis procedure with single evaluation by a physician or other qualified health care professional

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
94004	XXX	1.00	**RUC Time**	39945

CPT Descriptor 2 Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; nursing facility, per day

Other Reference CPT Code	Global	Work RVU	Time Source
93283	XXX	1.15	**RUC Time**

CPT Descriptor Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead implantable cardioverter-defibrillator system

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 9 **% of respondents:** 29.0 **%**

TIME ESTIMATES (Median)	**CPT Code: 88380**	**Key Reference CPT Code:** 88173	**Source of Time** RUC Time

Median Pre-Service Time	0.00	15.00
Median Intra-Service Time	33.00	25.00
Median Immediate Post-service Time	0.00	10.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**33.00**	**50.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.44	3.56
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.89	3.67
Urgency of medical decision making	3.33	3.78
Technical Skill/Physical Effort (Mean)		
Technical skill required	4.00	3.56
Physical effort required	3.78	3.44
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	2.89	3.78
Outcome depends on the skill and judgment of physician	4.22	4.00
Estimated risk of malpractice suit with poor outcome	3.56	3.89

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	3.78	3.44
Intra-Service intensity/complexity	3.89	3.67
Post-Service intensity/complexity	4.22	4.00

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

Background

In September 2005, the RUC began a process of identifying services that represent new technology as the codes were presented to the Committee. Beginning in October 2013 the RUC started to review the codes that were initially valued from September 2008-April 2009 with three years of available claims data (2010, 2011 and preliminary 2012 data). Two microdissection services (88380-1) were reviewed by the RUC in February 2007, represented new technology, and were published in CPT 2008. Microdissection techniques have revolutionized the ability of pathologists to fully utilize the power of current molecular technologies, including PCR, microarrays, proteomics, and next generation sequencing. For CY 2014 the physician work relative values and physician time are shown below:

88380-Microdissection (ie, sample preparation of microscopically identified target); laser capture (Work RVU = 1.56, Intra-Service Time = 45 minutes)
88381-Microdissection (ie, sample preparation of microscopically identified target); manual (Work RVU = 1.18, Intra-Service Time = 30 minutes)

Survey Effort and Results

The College of American Pathologists (CAP) and the American Society for Clinical Pathology (ASCP) performed a targeted and random survey of nearly13,000 members. This targeted and random survey effort was necessary to establish representative and accurate survey results. ASCP performed a survey of 10,000 members which encompassed the majority of its membership. There were three respondents for 88380 and four respondents for 88381from ASCP's effort. CAP surveyed 2,600 random members and 261 targeted members. The targeted group consisted of identified CAP members who specialize in molecular services. Below are the survey results of CPT code 88380 broken down by the targeted and random survey respondents.

Random N=12

	Time			
	Pre	Intra	Post	Work RVU
Low	3	5	5	1.10
25%	5	11	5	1.13
Median	6	20	10	1.19
75%	9	36	15	1.42
High	10	60	20	1.45

Targeted N= 19

	Time			
	Pre	Intra	Post	Work RVU
Low	1	12	5	0.50
25%	5	20	5	1.19
Median	5	35	9	1.40
75%	10	53	20	1.50
High	15	75	30	1.59

Combined N= 31

	Time			
	Pre	Intra	Post	Work RVU
Low	1	5	5	0.50
25%	5	15	5	1.14
Median	5	28	10	1.35
75%	10	50	18	1.44
High	15	75	30	1.59

CAP and ASCP's expert panels reviewed the survey and developed its recommendations. CAP's expert panel included CAP's CPT/RUC Workgroup, its Economic Affairs Executive Committee, and other representatives from general and academic pathology practice settings. ASCP's experts were drawn from the members of its Commission on Public Policy. The expert panels reviewed the survey results from the 31 respondents and compared the recommended RVW, time and intensity/complexity of 88380 to the key reference service 88173 - Cytopathology, evaluation of fine

needle aspirate; interpretation and report - 1.39 RVUs and other pathology codes. It was noted first by the expert panels that the second most frequently chosen key reference services were 88323 - Consultation and report on referred material requiring preparation of slides - 1.83 RVUs and 88307 - Level V - Surgical pathology, gross & micro exam - 1.59 RVUs.

Many of the intensity and complexity measures indicated the physician work for 88380 is greater than 88173. The proposed RVU and physician times also compare favorable to the second and third most common key reference services. The magnitude of the intensity and complexity measures clearly indicate the greater intensity and complexity of the laser capture service in comparison to the manual microdissection service. The CAP and ASCP expert panels agreed that the survey work results of the combined survey captures the typical patient scenario work most accurately.

The survey median RVW was 1.35 with median time components of 5 minutes pre-service, 28 minutes intra, and 10 minutes post service. The expert panel believed the median work RVU of the survey respondents slightly over estimated the typical physician work of laser capture microdissection. In addition, the molecular experts consulted indicated the bulk of the physician work remains in the intra service period and post service work was not as high as 10 minutes. Therefore, CAP and ASCP's experts agreed, to account for the typical patient scenario, the pre-service and intra-service physician work are recommended to be combined into the intra-service period and the post-service time should be eliminated for this service. In addition, the physician work RVU represented by the 25th percentile survey results of 1.14 work RVUs is most appropriate for this service. CAP and ASCP recognize that this recommended work RVU represents a 27% decrease from the current work RVU of 1.56, as well as a 27% decrease in the physician time.

The CAP and ASCP recommend a physician work RVU of 1.14 with 33 minutes of physician intra-service time for CPT code 88380.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: Yes

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☒ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☒ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 88380

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Pathology How often? Rarely

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 2000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. Medicare typically represents 50% of these services. Pathologists and clinical laboratories primarily provide this service. Specialty percentages obtained from the RUC Database.

Specialty Pathology Frequency 1500 Percentage 75.00 %

Specialty Clinical Laboratory Frequency 500 Percentage 25.00 %

Specialty Frequency 0 Percentage 0.00 %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 153
If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. Database

Specialty Pathology Frequency 115 Percentage 75.16 %

Specialty Clinical Laboratory Frequency 38 Percentage 24.83 %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? No

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Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Tests

BETOS Sub-classification:
Lab tests

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 88380

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:88381 Tracking Number Original Specialty Recommended RVU: **0.53**
Presented Recommended RVU: **0.53**
Global Period: XXX RUC Recommended RVU: **0.53**

CPT Descriptor: Microdissection (ie, sample preparation of microscopically identified target); manual

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 67 year old female, with a small lung mass undergoes a core needle biopsy which demonstrates adenocarcinoma of the lung. Sections from the tissue block are sent to the molecular laboratory for EGFR mutation testing.

Percentage of Survey Respondents who found Vignette to be Typical: 98%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting?
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting?
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: N/A

Description of Intra-Service Work: Following comparison with adjacent stained sections from the same tissue block, areas of adenocarcinoma tumor cells in the background of normal lung cellular parenchyma and inflammation are microscopically identified and marked by the pathologist. The pathologist counts a representative sample of tumor and non-neoplastic cells in the circled area to estimate the proportion of tumor cells in the microdissected area. The tumor cells are manually obtained from all the marked areas for DNA extraction (by the technologist) and analysis for EGFR mutations.

Description of Post-Service Work: N/A

SURVEY DATA

RUC Meeting Date (mm/yyyy)	02/2014				
Presenter(s):	Jonathan L. Myles, MD, Lee Hilborne, MD, Mahesh Mansukhani, MD				
Specialty(s):	College of American Pathologists and American Society of Clinical Pathology				
CPT Code:	88381				
Sample Size:	12861	**Resp N:**	64	**Response:** 0.4 %	
Description of Sample:	Random andd Targeted				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	10.00	20.00	**50.00**	100.00	1200.00
Survey RVW:	0.30	0.53	**0.74**	0.86	1.40
Pre-Service Evaluation Time:			**5.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	3.00	10.00	**15.00**	25.00	50.00

Immediate Post Service-Time:	**5.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

XXX Global Code

CPT Code:	88381	**Recommended Physician Work RVU: 0.53**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**0.00**	**0.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**20.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

XXX Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
88363	XXX	0.37	**RUC Time**

CPT Descriptor Examination and selection of retrieved archival (ie, previously diagnosed) tissue(s) for molecular analysis (eg, KRAS mutational analysis)

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
76536	XXX	0.56	**RUC Time**	694,976

CPT Descriptor 1 Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
93224	XXX	0.52	**RUC Time**	489,949

CPT Descriptor 2 External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional

Other Reference CPT Code	Global	Work RVU	Time Source
95925	XXX	0.54	**RUC Time**

CPT Descriptor Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 18 **% of respondents:** 28.1 **%**

TIME ESTIMATES (Median)	**CPT Code: 88381**	**Key Reference CPT Code:** 88363	**Source of Time RUC Time**
Median Pre-Service Time	0.00	0.00	
Median Intra-Service Time	20.00	17.00	
Median Immediate Post-service Time	0.00	0.00	
Median Critical Care Time	0.0	0.00	
Median Other Hospital Visit Time	0.0	0.00	
Median Discharge Day Management Time	0.0	0.00	
Median Office Visit Time	0.0	0.00	
Prolonged Services Time	0.0	0.00	
Median Subsequent Observation Care Time	0.0	0.00	
Median Total Time	**20.00**	**17.00**	
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES (Mean)		**(of those that selected Key Reference code)**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.00	2.94
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.00	2.94
Urgency of medical decision making	3.28	3.06
Technical Skill/Physical Effort (Mean)		
Technical skill required	3.33	3.17
Physical effort required	2.89	2.61
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	3.17	2.89
Outcome depends on the skill and judgment of physician	3.50	3.17
Estimated risk of malpractice suit with poor outcome	3.17	2.72

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	3.28	3.06
Intra-Service intensity/complexity	3.22	3.06

Post-Service intensity/complexity	3.28	3.11

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

Background

In September 2005, the RUC began a process of flagging services that represent new technology as the codes were presented to the Committee. Beginning in October 2013 the RUC started to review the codes that were valued between September 2008-April 2009 with three years of available claims data (2010, 2011 and preliminary 2012 data). Two microdissection services (88380-1) were reviewed by the RUC in February 2007, represented new technology, and were published in CPT 2008. Microdissection techniques have revolutionized the ability of pathologists to carry out molecular analysis to fully utilize the power of current molecular technologies, including PCR, microarrays, proteomics, and next generation sequencing. For CY 2014 the physician work relative values and physician time are shown below:

88380-Microdissection (ie, sample preparation of microscopically identified target); laser capture (Work RVU = 1.56, Intra-Service Time = 45 minutes)
88381-Microdissection (ie, sample preparation of microscopically identified target); manual (Work RVU = 1.18, Intra-Service Time = 30 minutes)

Survey Effort and Results

The College of American Pathologists (CAP) and the American Society for Clinical Pathologists (ASCP) performed a targeted and random survey of nearly13,000 members. This targeted and random survey effort was necessary to establish representative and accurate survey results. ASCP performed a survey of 10,000 members which encompassed the majority of its membership. There were three respondents for 88380 and four respondents for 88381 from ASCP's effort. CAP surveyed 2,600 random members and 261 targeted members. The targeted group consisted of identified CAP members who specialize in molecular services. Below are the survey results of CPT code 88381 broken down by the targeted and random survey respondents.

Random N=11

	Time			
	Pre	Intra	Post	Work RVU
Low	2	10	4	0.30
25%	2	15	5	0.65
Median	5	20	5	0.80
75%	5	28	10	0.86
High	10	40	20	1.20

Targeted N=53

	Time			
	Pre	Intra	Post	Work RVU
Low	1	3	2	0.35
25%	3	10	4	0.50
Median	5	15	5	0.70
75%	5	25	10	0.87
High	10	50	20	1.40

Combined N=64

	Time			
	Pre	Intra	Post	Work RVU
Low	1	3	2	0.30
25%	3	10	5	0.53
Median	5	15	5	0.74
75%	5	25	10	0.86
High	10	50	20	1.40

CAP and ASCP's expert panels reviewed the survey and developed its recommendations. CAP's expert panel included CAP's CPT/RUC Workgroup, its Economic Affairs Executive Committee, and other representatives from general and academic pathology practice settings. ASCP's experts were drawn from the members of its Commission on Public Policy. The expert panels reviewed the survey results from the 64 respondents and compared the recommended RVW, time and intensity/complexity of 88381 to the key reference service 88363 - Examination and selection of retrieved archival tissue(s) for molecular analysis - 0.37 RVUs and other pathology codes. It was noted first by the expert panels that the second most frequently chosen key reference service was 88331 - Pathology consultation during surgery; first tissue block, with frozen section(s), single specimen - 1.19 RVUs. Secondly, the expert panel noted that the median and 25th percentile work RVUs were greater than the key reference service's RVUs indicating the physician work for 88381 is greater than 88363.

In addition, all of the intensity and complexity measures indicated the physician work for 88381 is greater than 88363. Together with the strong response rate and the consistency of the survey respondent's results, the CAP and ASCP expert panels are in agreement that although there are many instances where the time, intensity, and complexity of the work may warrant an RVU of 0.70 or above, the typical patient service at this time reflects a slightly lower work RVU. The CAP and ASCP expert panel agreed that the 25th percentile survey work results of the combined survey captures the typical patient scenario most accurately.

The survey median RVW was 0.74 with median time components of 5 minutes pre-service, 15 minutes intra, and 5 minutes post service. The expert panel believed the median work RVU of the survey respondents slightly over estimated the typical physician work of manual microdissection. In addition, the molecular experts consulted indicated the bulk of the physician work remains in the intra service period and post service work was minimal. Therefore, CAP and ASCP's experts agreed, to be consistent with other pathology services, and to account for only the typical patient scenario, the pre-service and intra-service physician work are recommended to be combined into the intra-service period and the post-service time should be eliminated. In addition, the physician work RVU represented by the 25th percentile survey results of 0.53 work RVUs is most appropriate for this service. CAP and ASCP recognize that this recommended work RVU represents a 55% decrease from the current work RVU of 1.18.

The CAP and ASCP recommend a physician work RVU of 0.53 with 20 minutes of physician intra-service time for CPT code 88381.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.

☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 88381

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Pathology How often? Sometimes

Specialty Clinical Laboratory How often? Sometimes

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 50000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. Medicare typically represents 50% of these services. Pathologists and clinical laboratories primarily provide this service. With the growth in molcular pathology services, it is anticipated that there will be continued growth in these services. Specialty percentages obtained from the RUC Database.

Specialty Clinical Laboratory Frequency 43500 Percentage 87.00 %

Specialty Pathology Frequency 6500 Percentage 13.00 %

Specialty Frequency 0 Percentage 0.00 %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 22,007 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. Database

Specialty Clinical Laboratory Frequency 19000 Percentage 86.33 %

Specialty Pathology Frequency 3007 Percentage 13.66 %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? No

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Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Tests

BETOS Sub-classification:
Lab tests

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 88381

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

SS Rec Summary

ISSUE: Microdissection

TAB: 29

Source	CPT	DESC	Resp	IWPUT	RVW					Total	PRE-TIME			INTRA-TIME					IMMD
					MIN	25th	MED	75th	MAX	Time	EVAL	POSIT	SDW	MIN	25th	MED	75th	MAX	POST
REF	88173	Cytopathology, evaluation of fine needle aspirate; interpretation and report	58	0.033			1.39			50	15					25			10
CURRENT	88380	Microdissection (ie, sample preparation of microscopically identified target); laser capture	11	0.035			1.56			45						45			
SVY	88380	Microdissection (ie, sample preparation of microscopically identified target); laser capture	31	0.036	0.50	1.14	1.35	1.44	1.59	43	5			5	15	28	50	75	10
REC	88380	Microdissection (ie, sample preparation of microscopically identified target); laser capture	31	0.035			1.14			33						33			

Source	CPT	DESC	Resp	IWPUT	RVW					Total	PRE-TIME			INTRA-TIME					IMMD
					MIN	25th	MED	75th	MAX	Time	EVAL	POSIT	SDW	MIN	25th	MED	75th	MAX	POST
REF	88363	Examination and selection of retrieved archival (ie, previously diagnosed) tissue(s) for molecular analysis (eg, KRAS mutational analysis)	87	0.022			0.37			17						17			
CURRENT	88381	Microdissection (ie, sample preparation of microscopically identified target); manual	18	0.039			1.18			30						30			
SVY	88381	Microdissection (ie, sample preparation of microscopically identified target); manual	64	0.034	0.30	0.53	0.74	0.86	1.40	25	5			3	10	15	25	50	5
REC	88381	Microdissection (ie, sample preparation of microscopically identified target); manual	64	0.027			0.53			20						20			

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:
88380- Microdissection (ie, sample preparation of microscopically identified target); laser capture
88381- Microdissection (ie, sample preparation of microscopically identified target); manual

Global Period: XXX Meeting Date: January/February 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

Data were developed by the College of American Pathologists (CAP) and the American Society of Clinical Pathology (ASCP) relative value workgroups. The workgroups consisted of representatives from the general and academic pathology community and members with molecular pathology experience and expertise. The collected and recommended practice expense inputs were also reviewed by CAP's economic affairs and executive committees.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: The current direct practice expense inputs listed in CMS' database for 88380-1 are used as a reference.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:

No other additional minutes beyond the subcommittee's standards are recommended.

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:

These services are maturing whereas the typical work of the technologist has changed. Apparent in the physician work survey, the technologist is now typically spending more time and the pathologist is spending less time.

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

The specimen is accessioned prepared for examination. Slides are assembled and the block is retrieved and prepared for processing. The specimen is then processed for H&E slide preparation (including refacing the block and preparing for cutting, step sectioning and additional cuts. Routine staining is performed, coverslipping, quality control functions are initiated by maintaining specimen tracking logs and labeling.

Other Activity (please specify)

Intra-Service Clinical Labor Activities:

The slides are assembled according to standard lab procedures. Paperwork is completed. Slides and paperwork are delivered to pathologists for H&E examination and target selection.

Slides and paperwork then retrieved and delivered to the laboratory after target selection.

Deparaffination is performed on unstained slides (typical for EGFR is 8 slides; 10 for laser)
Methylene blue staining is performed on unstained slides.

Examination of methylene blue stained slides to verify and visualize targets; etch slide with diamond tipped marker

Collect and label tubes for target

Decontamination of workspace and dissecting microscope

For CPT code 88380, the laser capture instrument is prepared, quality control and maintenance functions are performed.

Microdissect each unstained slide sequentially while reviewing H and E stained slide (please break out the individual steps for this line)

Incubation buffer: Thaw proteinase K and DDT. Add 100 uL of proteinase K and 100 uL of DTT to 800 uL of incubation buffer (can use for 10 cases)

For 88380:

1. Turn on Laser microscope.
2. Adjust settings (laser power, etc. to suit case).
3. Place a "CapSure" LCM cap (Arcturus) on system OR add 25uL of incubation buffer into cap of 500 microliter tube, carefully invert and move into place on slide (PALM dissecting microscope).
4. Adjust image; choose magnification (will vary by arrangement of tumor cells – single cells versus tiny clusters),
5. Blast cells individually or in clusters onto "CapSure" LCM cap (Arcturus) or into buffer (PALM).
6. Continue until all cells on slide have been captured.
7. Move CapSure cap or centrifuge tube cap off slide; change slide.
8. Repeat until enough cells have been captured.
9. Remove CapSure Cap from Laser microscope, place in centrifuge tube containing 100 microliters lysis buffer ("incubation buffer") with proteinase K. Invert tube and incubate at 55C overnight (Arcturus) OR remove centrifuge tube from laser instrument, carefully cap the tube without losing liquid, spin to collect lysis buffer at bottom of tube. Add enough lysis buffer with proteinase K to bring to 100 microliters, incubate overnight.
10. Transport to automated extractor.

For 88381:
1) Turn on dissecting microscope
2) Place slide on scope

3) Add 60uL of incubation buffer into cap of tube and 40uL of incubation buffer to tube
3) Remove razor blade from box
4) Microdissect tissue within etched area, while viewing slide under dissecting scope
5) Place tissue into cap of collection tube with blade
6) Repeat steps 4 and 5 for seven other slides
7) Throw away razor blade
8) Cap tube and vortex
9) Visually inspect tube to make sure microdissected material at bottom of tube
10) Place tape on tube
11) Place parafilm over tube lid
12) Add to 55 degree waterbath overnight, after which tube will be transported to automated DNA extractor

Common to both:
Document procedure in logs and place tubes in storage until extraction
Other Activity (please specify)

Write down elution volume for extraction.

Post-Service Clinical Labor Activities:
Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable)

Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste

Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure)

Manage any relevant utilization review/quality assurance activities and regulatory compliance documentation.

	A	B	C	D	E	F	G
1				Current Inputs		Recommended Inputs	
2	SEE NOTES Column H			88380	88381	88380	88381
3	**Meeting Date: Jan - Feb 2014 Tab: 29 Specialty: Pathology**	**CMS Code**	**Staff Type**	**Microdissection (ie, sample preparation of microscopically**	**Microdissection (ie, sample preparation of microscopically**	**Microdissection (ie, sample preparation of microscopically**	**Microdissection (ie, sample preparation of microscopically**
4	**LOCATION**			**Non Fac**	**Non Fac**	**Non Fac**	**Non Fac**
5	**GLOBAL PERIOD**			**XXX**	**XXX**	**XXX**	**XXX**
6	**TOTAL CLINICAL LABOR TIME**			**96.5**	**106.5**	**94.0**	**106.0**
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**	**LO33A**	**Labtech**	**5.5**	**5.5**	**2.5**	**2.5**
8	**TOTAL PRE-SERV CLINICAL LABOR TIME**	**L037B**	**Histotech**	**32.0**	**32.0**	**14.5**	**14.5**
9	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**	**LO33A**	**Labtech**	**4.0**	**4.0**	**2.0**	**2.0**
10	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**	**LO45A**	**Cytotech**	**47.0**	**57.0**	**72.0**	**84.0**
11	**TOTAL POST-SERV CLINICAL LABOR TIME**	**LO33A**	**Labtech**	**8.0**	**8.0**	**3.0**	**3.0**
12	**PRE-SERVICE**						
13	**Start: Following visit when decision for surgery or procedure made**						
14	Prepare specimen containers/preload fixative/label containers/distributre requisition form(s) to physician						
15	Accession specimen/prepare for examination, assemble slides	**LO33A**	**Labtech**	3	3	1.5	1.5
16	Perform screening function (where applicable)						
17	Prepare room. Filter and replenish stains and supplies.						
18	Other Clinical Activity (please specify): Retrieve block.	**LO33A**	**Labtech**	2.5	2.5	1	1
19	Process specimen for H&E slide preparation (includes refacing block and preparing for cutting, step sectioning and recuts, routine staining, coverslipping, quality control function, maintaining specimen tracking logs and labeling.)	**L037B**	**Histotech**	32	32	14.5	14.5
20							
21	**End: When specimen is ready for examination by pathologist**						
22	**SERVICE PERIOD**						
23	**Start: When patient enters office/facility for surgery/procedure:**						
24	Assemble and deliver slides with paperwork to pathologists for H&E examination and target selection	**LO33A**	**Labtech**	2	2	1	1
25	Slides and paperwork delivered to the laboratory after target selection	**L033A**	**Labtech**	2	2	1	1
26	Deparaffination of unstained slides	**LO45A**	**Cytotech**	15	15	15	15
27	Methylene blue staining of 10 (laser) and 8 (manual) slides	**LO45A**	**Cytotech**			8	8
28	Examination of ~~un~~stained ~~stains~~ slides ~~to~~ to verify and visualize targets; ~~mark with pen~~	**LO45A**	**Cytotech**	8	8	8	8
29	Etch slide with diamond tipped marker	**LO45A**	**Cytotech**			3	3
30	Collect and label tubes for target	**LO45A**	**Cytotech**	2	2	1	1
31	Decontamination of workspace and dissecting scope	**LO45A**	**Cytotech**	0	3	0	3
32	Prepare Laser instrument, quality control and maintenance functions	**LO45A**	**Cytotech**	3	0	3	0
33	Microdissect each ~~un~~stained slide sequentially while reviewing H and E stained slide	**LO45A**	**Cytotech**	15	25	30	42
34	Prepare Incubation buffer: Thaw proteinase K and DDT. Add 100 uL of proteinase K and 100 uL of DTT to 800 uL of incubation buffer (can use for 10 cases). Add 60uL of incubation buffer into cap of tube and 40uL of incubation buffer to tube.	**LO45A**	**Cytotech**			6	6
35	~~Turn on dissecting microscope, place slide on scope,~~ remove razor blade from box. Microdissect tissue within etched area, while viewing slide under dissecting scope, place tissue into cap of collection tube with blade. Repeat this step for seven other slides.	**LO45A**	**Cytotech**			18	30
36	~~Dispose of razor blade, cap tube and vortex specimens.~~ Visually inspect tube to make sure microdissected material are at the bottom of tube.	**LO45A**	**Cytotech**			3	3
37	Place tape on tube, place parafilm over tube lid. Add to 55 degree waterbath overnight, after which tube will be transported to automated DNA extractor.	**LO45A**	**Cytotech**			3	3
38	Document procedure in logs and place tubes in storage until extraction	**LO45A**	**Cytotech**	4	4	4	4
39	Other Activity (please specify)						
40							
41	**Intra-service**						
42	Assist pathologist with gross specimen examination (including performance of intraoperative frozen sections)						
43	**Post-Service**						
44	Prepare specimen for automated processing						
45	~~Process specimen for slide preparation (includes staining,~~ coverslipping, quality control function, maintaining specimen ~~tracking, logs and labeling)~~						
46	Assemble and deliver slides with paperwork to pathologists						
47	Clean room/equipment whiile performing service						
48	Coordinate care						
49	Other Activity (please specify)						
50	**End: When specimen examination by pathologist is complete**						
51	**POST-SERVICE Period**						
52	**Start: When specimen examination by pathologist is complete**						

	A	B	C	D	E	F	G
1				Current Inputs		Recommended Inputs	
2	SEE NOTES Column H			88380	88381	88380	88381
3	**Meeting Date: Jan - Feb 2014 Tab: 29 Specialty: Pathology**	**CMS Code**	**Staff Type**	**Microdissection (ie, sample preparation of microscopically**	**Microdissection (ie, sample preparation of microscopically**	**Microdissection (ie, sample preparation of microscopically**	**Microdissection (ie, sample preparation of microscopically**
4	**LOCATION**			**Non Fac**	**Non Fac**	**Non Fac**	**Non Fac**
5	**GLOBAL PERIOD**			**XXX**	**XXX**	**XXX**	**XXX**
53	Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable)	**LO33A**	**Labtech**	6	6	2	2
54	Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste	**LO33A**	**Labtech**	2	2	1	1
55	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure)	**LO33A**	**Labtech**			1	1
56	Manage any relevant utilization review/quality assurance activities and regulatory compliance documentation						
57	Submit/receive material for consultation (where applicable)						
58	Other Activity (please specify)						
59	**End: When specimen, chemical waste and record handling is complete**						
60	**MEDICAL SUPPLIES****	**CODE**	**UNIT**				
61	gloves, sterile	**SB024**	**pair**	**4**	**4**	**4**	**4**
62	blade, microtome	**SF004**	**item**	**2**	**2**	**1**	**1**
63	blade, sharp pointed surgical	**SF053**	**item**		**6**	**2**	**2**
64	canned air (Dust-Off)	**SK097**	**oz**		**1**		
65	cover slip, glass	**SL030**	**item**	**2**	**2**	**1**	**1**
66	slide, microscope	**SL122**	**item**	**2**	**2**	**11**	**9**
67	stain, frozen section, H&E (1ml per slide)	**SL134**	**ml**	**2**	**2**	**0**	**0**
68	stain, eosin	**SL201**	**ml**			**1**	**1**
69	stain, hematoxylin	**SL135**	**ml**			**1**	**1**
70	xylenes solvent	**SL151**	**ml**	**100**	**100**	**100**	**100**
71	ethanol, 100%	**SL189**	**ml**	**100**	**100**	**100**	**100**
72	ethanol, 70%	**SL190**	**ml**	**100**	**100**	**100**	**100**
73	tube, centrifuge, micro, 1.5 ml, DNase free snap lock	**SL240**	**item**	**6**	**6**	**2**	**2**
74	buffer, lysis	**SL246**	**ml**		**50**	**0.05**	**0.05**
75	caps, Capsure Macro LCM	**SL247**	**ml**	**2**		**2**	
76	ethanol, 95%	**SL248**	**ml**	**100**	**100**	**100**	**100**
77	glycerol, 3%	**SL249**	**ml**	**100**	**100**	**0**	**0**
78	methylene blue stain	**SL250**	**ml**	**6**		**11**	**8**
79	Rnase-free water	**SL251**	**ml**		**50**		**50**
80	slide, microscope, sterile	**SL252**	**item**	**6**	**6**	**0**	**0**
81	Surface Decontaminant (DNA Away)	**Invoice**	**ml**			**2**	**2**
82	mounting media (Histomount)	**SL095**	**ml**			**2**	**2**
83	label for microscope slides	**SL085**	**item**			**10**	**4**
84	eye shield, non-fog	**SG049**	**item**			**1**	**1**
85	gauze, non-sterile 4in x 4in	**SG051**	**item**			**4**	**4**
86	wipes, lens cleaning (per wipe) (Kimwipe)	**SM027**	**item**			**1**	**1**
87							
88	**EQUIPMENT**	**CODE**					
89	microscope, binocular - dissecting	**EP023**			**28**		**43**
90	microscope, compound	**EP024**		**5**	**5**	**8**	**8**
91	slide etcher-labeler	**EP035**		**32**	**32**	**4**	**4**
92	instrument, microdissection (Veritas)	**EP087**		**40**		**34**	
93	microtome	**ER041**		**32**	**32**	**11**	**8**
94	hood, fume	**EP017**				**29.5**	**29.5**
95	slide stainer, automated high-volume throughput	**EP036**				**2**	**2**
96	water bath, FISH procedures (lab)	**EP054**				**13**	**13**
97	solvent recycling system	**EP038**				**4**	**4**
98	slide coverslipper, robotic	**EP033**				**1**	**1**
99	vortexer					**0.5**	**0.5**

AMA/Specialty Society RVS Update Committee Summary of Recommendations
CMS-Other - Utilization over 250,000 screen

January 2014

Doppler Echocardiography

The Relativity Assessment Workgroup identified these services through the CMS/Other Source – Utilization over 250,000 screen. In October 2013, the RUC noted that these services were never RUC reviewed but are frequently reported. The RUC recommended that these services be surveyed for physician work and develop direct practice expense inputs for the January 2014 RUC meeting.

93320 ***Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete***
The RUC reviewed the survey results from 60 physicians and recommends maintaining the work RVU of 0.38 for CPT code 93320 as the physician work has not changed. The specialty societies indicated and the RUC agreed that 15 minutes of intra-service time, adequately accounts for the physician time required to perform this service. There is no pre- or post-service time associated with this code because it is an add-on code which describes the additional work of complete pulsed wave and/or continuous wave Doppler.

The RUC compared the surveyed code to key reference service 93308 *Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study* (work RVU=0.53, 15 minutes intra-service), with identical intra-service time and similar intensity. Although 93308 is an XXX code, respondents are more familiar with the commonly performed complete transthoracic echocardiography that includes pulsed wave and/or continuous wave Doppler. The higher RVU for 93308 is accounted for by the 5 minutes of pre- and post-service time. To support the recommended value the RUC also compared the surveyed code to ZZZ global services that require 15 minutes of physician intra-service time, CPT code 95885 *Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; limited (List separately in addition to code for primary procedure)* (work RVU=0.35), and CPT code 88177 *Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, each separate additional evaluation episode, same site (List separately in addition to code for primary procedure)* (work RVU=0.42). **The RUC recommends a work RVU of 0.38 for CPT code 93320.**

93321 ***Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List separately in addition to codes for echocardiographic imaging)***
The RUC reviewed the survey results from 50 physicians and recommends maintaining the work RVU of 0.15 for CPT code 93321 as the physician work has not changed. The specialty societies indicated and the RUC agreed that 10 minutes of intra-service time, adequately accounts

for the physician time required to perform this service. There is no pre- or post-service time associated with this code because it is an add-on code which describes the additional work of limited pulsed wave and/or continuous wave Doppler.

To support the recommended value the RUC also compared the surveyed code to ZZZ, MPC code 96367 *Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)* (work RVU=0.19). The comparison code 96367 is more intense and complex than 93321, accounting for the higher work value. **The RUC recommends a work RVU of 0.15 for CPT code 93321.**

93325 *Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)*
The RUC reviewed the survey results from 50 physicians and recommends maintaining the work RVU of 0.07 for CPT code 93325 as the physician work has not changed. The specialty societies indicated and the RUC agrees that 10 minutes of intra-service time, adequately accounts for the physician time required to perform this service. There is no pre- or post-service time associated with this code because it is an add-on code which describes the work of Doppler color flow velocity mapping.

To support the recommended value the RUC also compared the surveyed code to ZZZ, MPC code 96375 *Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)* (work RVU=0.10). The comparison code 96367 is more intense and complex than 93325, accounting for the higher work value. **The RUC recommends a work RVU of 0.07 for CPT code 93325.**

Practice Expense
The RUC reviewed and approved the direct practice expense inputs with minor modifications as approved by the Practice Expense Subcommittee.

CPT Code (•New)	CPT Descriptor	Global Period	Work RVU Recommendation
93320	Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete	ZZZ	0.38 (No Change)
93321	Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List separately in addition to codes for echocardiographic imaging)	ZZZ	0.15 (No Change)
93325	Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)	ZZZ	0.07 (No Change)

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:93320 Tracking Number Original Specialty Recommended RVU: **0.38**
Presented Recommended RVU: **0.38**
Global Period: ZZZ RUC Recommended RVU: **0.38**

CPT Descriptor: Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 54 year-old woman with rheumatic mitral stenosis complains of increasing dyspnea. A complete echo previously showed moderate mitral stenosis with an estimated mitral valve area of 1.3 cm^2. The patient subsequently undergoes exercise bicycle stress testing with serial Doppler imaging.

A complete baseline pulsed wave and continuous wave Doppler examination is performed. Continuous wave Doppler is used during exercise to assess changes in mean mitral valve gradient and pulmonary artery pressure with increasing heart rate.

Percentage of Survey Respondents who found Vignette to be Typical: 82%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 29%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 7%

Description of Pre-Service Work:

Description of Intra-Service Work: Digitally recorded flow velocity data are reviewed. Multiple functional measurements are reviewed, including: pressure gradients, stenotic valve areas, quantitation of regurgitation (regurgitant volume, regurgitant fraction, and effective orifice area), global left and right ventricular systolic performance, and diastolic function. Right ventricular systolic pressure is calculated. The findings are compared to previous studies, if available, to determine if there has been improvement or deterioration in these measures.

Description of Post-Service Work:

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014		
Presenter(s):	Richard Wright, MD; Michael Main, MD		
Specialty(s):	ACC, ASE		
CPT Code:	93320		
Sample Size:	591	**Resp N:** 60	**Response:** 10.1 %
Description of Sample:	random sample: half from ASE, half from ACC		

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	5.00	**87.50**	500.00	9837.00
Survey RVW:	0.15	0.49	**0.70**	0.85	5.00
Pre-Service Evaluation Time:			**9.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	3.00	10.00	**15.50**	20.00	60.00

Immediate Post Service-Time:	**10.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

ZZZ Global Code

CPT Code:	93320	**Recommended Physician Work RVU: 0.38**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**0.00**	**0.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**15.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

ZZZ Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? Yes

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
93308	XXX	0.53	**RUC Time**

CPT Descriptor Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
95874	ZZZ	0.37	**RUC Time**	59,754

CPT Descriptor 1 Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
96411	ZZZ	0.20	**RUC Time**	255,655

CPT Descriptor 2 Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)

Other Reference CPT Code	Global	Work RVU	Time Source
75565	ZZZ	0.25	**RUC Time**

CPT Descriptor Cardiac magnetic resonance imaging for velocity flow mapping (List separately in addition to code for primary procedure)

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 21 **% of respondents:** 35.0 **%**

TIME ESTIMATES (Median)	**CPT Code: 93320**	**Key Reference CPT Code: 93308**	**Source of Time RUC Time**
Median Pre-Service Time	0.00	5.00	
Median Intra-Service Time	15.00	15.00	
Median Immediate Post-service Time	0.00	5.00	
Median Critical Care Time	0.0	0.00	
Median Other Hospital Visit Time	0.0	0.00	
Median Discharge Day Management Time	0.0	0.00	
Median Office Visit Time	0.0	0.00	
Prolonged Services Time	0.0	0.00	
Median Subsequent Observation Care Time	0.0	0.00	
Median Total Time	**15.00**	**25.00**	
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**
Mental Effort and Judgment (Mean)	
The number of possible diagnosis and/or the number of management options that must be considered	4.10	4.19
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	4.38	4.19
Urgency of medical decision making	3.76	3.62
Technical Skill/Physical Effort (Mean)	
Technical skill required	4.38	4.19
Physical effort required	3.19	3.14
Psychological Stress (Mean)	
The risk of significant complications, morbidity and/or mortality	3.90	3.76
Outcome depends on the skill and judgment of physician	4.48	4.33
Estimated risk of malpractice suit with poor outcome	3.90	4.00

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	2.81	2.90
Intra-Service intensity/complexity	4.00	3.90

Post-Service intensity/complexity	3.19	3.24

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

In April 2013, the RUC lowered the threshold of the CMS/Other screen to Medicare utilization of 250,000 or more. This screen captured related echocardiography add-on code 93325 for color flow velocity mapping. In accordance with the RAW and the RUC, the societies have prepared recommendations for a family of three echocardiography add-on codes.

Few ZZZ codes exist in the range of the current values for these services. Fewer still exist with which cardiologists are familiar. In preparation for this survey, we submitted a reference service list that mixed ZZZ and XXX codes to the Research Subcommittee for review. The Subcommittee agreed that few familiar ZZZ codes were available and felt the mixed reference service list provided an appropriate spectrum of services for survey respondents.

The first service is add-on code 93320 which describes the additional work of complete pulsed wave and/or continuous wave Doppler. This code can be reported with congenital transthoracic echocardiography, transesophogeal echocardiography, or stress echocardiography. When performed with a complete transthoracic echocardiography, it is bundled into code 93306.

A joint RVS panel of ACC and ASE physicians familiar with the service reviewed survey data. The survey was completed by physicians who have experience with the service. The key reference service is 93308, a follow-up or limited transthoracic echocardiography. Respondents who selected the key reference service felt 93320 was roughly as intense/complex as the key reference service, with some measures slightly higher and others slightly lower. While 93308 is an XXX code, this comparison makes sense; respondents would be familiar with the more commonly performed complete transthoracic echocardiography that includes pulsed wave and/or continuous wave Doppler (93306). The times and RVUs for the surveyed code and the reference code also align well since respondents felt they are comparable in intensity/complexity.

The key reference service was selected by 35% or respondents. Another 30% selected code 93015 that describes cardiovascular stress testing. This is a reasonable connection for respondents since a stress echocardiography study will sometimes include 93320.

To further establish the current value, we also compared 93320 to 75565, an add-on for cardiac MRI velocity flow mapping. Both codes describe components that are added to more comprehensive cardiovascular imaging services and align well at these times and RVUs with calculated intensities of 0.0253 and 0.0250 respectively.

Noting that the median intraservice time of 15.5 minutes nearly matches the existing intraservice time of 15 minutes, the societies recommend the current RVW of 0.38 with no preservice time, 15 minutes intraservice time, and no postservice time.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: Yes

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   ☒ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.

- ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
- ☐ Multiple codes are used to maintain consistency with similar codes.
- ☐ Historical precedents.
- ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 93320

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty cardiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 700000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. Double the 2012 Medicare utilization from the RUC database.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 350,000 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. 2012 Medicare utilization from the RUC database.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Imaging

BETOS Sub-classification:
Echography/ultrasonography

BETOS Sub-classification Level II:
Heart

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 93320

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:93321 Tracking Number Original Specialty Recommended RVU: **0.15**
Presented Recommended RVU: **0.15**
Global Period: ZZZ RUC Recommended RVU: **0.15**

CPT Descriptor: Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List separately in addition to codes for echocardiographic imaging)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 52 year-old woman who underwent pericardiocentesis 4 days ago reports increasing dyspnea, and a chest xray reveals cardiomegaly. A limited followup 2D echo shows a moderate pericardial effusion.

Pulsed wave Doppler of transmitral and transtricupid flow is used to assess for respiratory variation in inflow velocity consistent with tamponade physiology. Continuous wave Doppler of the tricuspid regurgitant jet is used to estimate pulmonary artery systolic pressure.

Percentage of Survey Respondents who found Vignette to be Typical: 92%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 14%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 3%

Description of Pre-Service Work:

Description of Intra-Service Work: Digitally recorded flow velocity data are reviewed. Appropriate functional measurement(s) specific to the clinical question are reviewed and compared to the Doppler data from prior echoes. This may include one or more of the following: pressure gradients, stenotic valve areas, quantitation of regurgitation (regurgitant volume, regurgitatant fraction, and effective orifice area), global left and right ventricular systolic performance, and/or diastolic function. Right ventricular systolic pressure is calculated. The findings are compared to previous studies to determine if there has been improvement or deterioration in these measures.

Description of Post-Service Work:

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014				
Presenter(s):	Richard Wright, MD; Michael Main, MD				
Specialty(s):	ACC, ASE				
CPT Code:	93321				
Sample Size:	591	**Resp N:**	50	**Response:** 8.4 %	
Description of Sample:	random sample: half from ASE, half from ACC				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	11.25	**42.50**	100.00	1200.00
Survey RVW:	0.15	0.46	**0.57**	0.70	4.00
Pre-Service Evaluation Time:			**5.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	0.00	5.00	**10.00**	20.00	30.00

Immediate Post Service-Time:	**5.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

ZZZ Global Code

CPT Code:	93321	**Recommended Physician Work RVU: 0.15**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**0.00**	**0.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**10.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

ZZZ Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? Yes

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
93308	XXX	0.53	**RUC Time**

CPT Descriptor Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
96367	ZZZ	0.19	**RUC Time**	2,045,039

CPT Descriptor 1 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
95874	ZZZ	0.37	**RUC Time**	59,754

CPT Descriptor 2 Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)

Other Reference CPT Code	Global	Work RVU	Time Source
93042	XXX	0.15	**RUC Time**

CPT Descriptor Rhythm ECG, 1-3 leads; interpretation and report only

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 34 **% of respondents:** 68.0 **%**

TIME ESTIMATES (Median)	**CPT Code: 93321**	**Key Reference CPT Code:** 93308	**Source of Time** **RUC Time**

Median Pre-Service Time	0.00	5.00
Median Intra-Service Time	10.00	15.00
Median Immediate Post-service Time	0.00	5.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**10.00**	**25.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	4.06	3.91
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	4.21	3.91
Urgency of medical decision making	4.68	3.85
Technical Skill/Physical Effort (Mean)		
Technical skill required	4.38	4.09
Physical effort required	2.97	2.85
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	4.24	3.85
Outcome depends on the skill and judgment of physician	4.59	4.29
Estimated risk of malpractice suit with poor outcome	4.47	4.06

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	2.73	2.61
Intra-Service intensity/complexity	3.73	3.58
Post-Service intensity/complexity	3.39	3.15

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

Add-on code 93321 describes the additional work of limited pulsed wave and/or continuous wave Doppler. This code can be reported with limited transthoracic echocardiography, congenital transthoracic echocardiography, transesophogeal echocardiography, or stress echocardiography.

A joint RVS panel of ACC and ASE physicians familiar with the service reviewed survey data. The survey was completed by physicians who have experience with the service. The key reference service is 93308, a follow-up or limited transthoracic echocardiography. Respondents who selected the key reference service felt 93321 was roughly as intense/complex as the key reference service. While 93308 is an XXX code, this comparison makes sense. Respondents would be familiar with the more commonly performed complete transthoracic echocardiography that includes pulsed wave and/or continuous wave Doppler (93306). The times and RVUs for the surveyed code and the reference code also align well since respondents felt they are comparable in intensity/complexity. The key reference service was selected by 68% of respondents.

To further establish the current value, we also compared 93321 to 93042 that describes the interpretation and report of a rhythm ECG. While 93042 is an XXX code, it has a shorter total time and an RVU equivalent to 93321.

Noting that the median intraservice time of 10 minutes exactly matches the existing intraservice time of 10 minutes, the societies recommend the current RVW of 0.15 with no preservice time, 10 minutes intraservice time, and no postservice time.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: Yes

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☒ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 93321

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty cardiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 234000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. Double the 2012 Medicare utilization from the RUC database.

Specialty cardiology Frequency 234000 Percentage 100.00 %

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 117,000 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. 2012 Medicare utilization from the RUC database.

Specialty cardiology Frequency 117000 Percentage 100.00 %

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Imaging

BETOS Sub-classification:
Echography/ultrasonography

BETOS Sub-classification Level II:
Heart

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 93321

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:93325 Tracking Number Original Specialty Recommended RVU: **0.07**
Presented Recommended RVU: **0.07**
Global Period: ZZZ RUC Recommended RVU: **0.07**

CPT Descriptor: Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 64 year old man with aortic valve endocarditis diagnosed one week ago by a complete tranthoracic echocardiogram complains of increasing dyspnea. A limited followup 2D echo shows an increase in size of the aortic valve vegetation and normal left ventricular systolic function.

Color Doppler is used to assess aortic regurgitation severity.

Percentage of Survey Respondents who found Vignette to be Typical: 92%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 21%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 8%

Description of Pre-Service Work:

Description of Intra-Service Work: Digitally recorded color flow images are reviewed. Assessment of the presence and severity of valve regurgitation, assessment of flow acceleration proximal to the regurgitant valve, assessment of flow acceleration within vessels and assessment of shunts and fistulae are all performed. The findings are compared to previous studies, if available, to determine if there has been improvement or deterioration in these images.

Description of Post-Service Work:

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014				
Presenter(s):	Richard Wright, MD; Michael Main, MD				
Specialty(s):	ACC, ASE				
CPT Code:	93325				
Sample Size:	591	**Resp N:**	50	**Response:** 8.4 %	
Description of Sample:	random sample: half from ASE, half from ACC				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	12.50	**75.00**	375.00	9837.00
Survey RVW:	0.07	0.26	**0.53**	0.70	5.00
Pre-Service Evaluation Time:			**2.50**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	0.00	5.25	**10.00**	15.00	60.00

Immediate Post Service-Time:	**5.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

ZZZ Global Code

CPT Code:	93325	**Recommended Physician Work RVU: 0.07**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**0.00**	**0.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**10.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

ZZZ Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? Yes

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
93308	XXX	0.53	**RUC Time**

CPT Descriptor Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
96367	ZZZ	0.19	**RUC Time**	2,045,039

CPT Descriptor 1 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
96375	ZZZ	0.10	**RUC Time**	1,786,088

CPT Descriptor 2 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)

Other Reference CPT Code	Global	Work RVU	Time Source
93042	XXX	0.15	**RUC Time**

CPT Descriptor Rhythm ECG, 1-3 leads; interpretation and report only

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 31 **% of respondents:** 62.0 **%**

TIME ESTIMATES (Median)	**CPT Code: 93325**	**Key Reference CPT Code:** 93308	**Source of Time** RUC Time

Median Pre-Service Time	0.00	5.00
Median Intra-Service Time	10.00	15.00
Median Immediate Post-service Time	0.00	5.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**10.00**	**25.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	4.00	4.03
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	4.07	4.00
Urgency of medical decision making	4.27	4.07
Technical Skill/Physical Effort (Mean)		
Technical skill required	4.43	4.27
Physical effort required	3.10	3.07
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	4.30	4.10
Outcome depends on the skill and judgment of physician	4.60	4.43
Estimated risk of malpractice suit with poor outcome	4.30	4.13

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	2.73	2.77
Intra-Service intensity/complexity	3.80	3.90
Post-Service intensity/complexity	3.47	3.47

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

Add-on code 93325 describes the work of Doppler color flow velocity mapping. This code can be reported with congenital transthoracic echocardiography, transesophogeal echocardiography, or stress echocardiography. When performed with a complete transthoracic echocardiography, it is bundled into code 93306.

A joint RVS panel of ACC and ASE physicians familiar with the service reviewed survey data. The survey was completed by physicians who have experience with the service. The key reference service is 93308, a follow-up or limited transthoracic echocardiography. Respondents who selected the key reference service felt 93325 was roughly as intense/complex as the key reference service, with some measures slightly higher and others slightly lower. While 93308 is an XXX code, this comparison makes sense. Respondents would be familiar with the more commonly performed complete transthoracic echocardiography that includes color flow Doppler (93306). 93308 would also be a code to which respondents would commonly append 93325. The times and RVUs for the surveyed code and the reference code also align well since respondents felt they are comparable in intensity/complexity. The key reference service was selected by 62% of respondents.

To further establish the current value within the cardiovascular family, we also compared 93325 to 93042 that describes the interpretation and report of a rhythm ECG. While 93042 is an XXX code, it has a shorter total time and an RVU higher than 93325. This resulting lower intensity for 93325 is appropriate.

Noting that the median intraservice time of 10 minutes nearly matches the existing CMS/Other intraservice time of 9 minutes, the societies recommend the current RVW of 0.15 with no preservice time, 10 minutes intraservice time, and no postservice time.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: Yes

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☒ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 93325

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty cardiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 946000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. Double the 2012 Medicare utilization from the RUC database.

Specialty cardiology Frequency 946000 Percentage 100.00 %

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 473,000 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. 2012 Medicare utilization from the RUC database.

Specialty cardiology Frequency 473000 Percentage 100.00 %

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Imaging

BETOS Sub-classification:
Echography/ultrasonography

BETOS Sub-classification Level II:
Heart

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 93325

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

SS Rec Summary

ISSUE: Echocardiography Add-on Codes

TAB: 30

Source	CPT	DESC	Resp	IWPUT	RVW MIN	RVW 25th	RVW MED	RVW 75th	RVW MAX	Total Time	PRE-TIME EVAL	PRE-TIME POSIT	PRE-TIME SDW	INTRA-TIME MIN	INTRA-TIME 25th	INTRA-TIME MED	INTRA-TIME 75th	INTRA-TIME MAX	IMMD POST
REF	93308	Echocardiogra	21	0.020			0.53			25	5					15			5
CURRENT	93320	Doppler echo		0.025			0.38			15						15			
SVY			60	0.018	0.15	0.49	0.70	0.85	5.00	34.5	9			3	10	15.5	20	60	10
REC				0.025			0.38			15						15			
COMP	75565	Cardiac magn		0.025			0.25			10						10			

Source	CPT	DESC	Resp	IWPUT	RVW MIN	RVW 25th	RVW MED	RVW 75th	RVW MAX	Total Time	PRE-TIME EVAL	PRE-TIME POSIT	PRE-TIME SDW	INTRA-TIME MIN	INTRA-TIME 25th	INTRA-TIME MED	INTRA-TIME 75th	INTRA-TIME MAX	IMMD POST
REF	93308	Echocardiogra	34	0.020			0.53			25	5					15			5
CURRENT	93321	Doppler echo		0.015			0.15			10						10			
SVY			50	0.035	0.15	0.46	0.57	0.70	4.00	20	5			0	5	10	20	30	5

CPT Code: 93320, 93321, 93325
Specialty Society(s) ACC, ASE

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor: 93320 Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete

Global Period: ZZZ Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee: A joint RUC advisory committee of members from ACC and ASE reviewed and amended the current PE inputs in light of the completed surveys.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: 93320 is an existing code and was used as the reference. Since 93320 is an add-on code, 93306 is also referenced to demonstrate what a complete procedure looks like.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time: N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence: N/A

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities: Retrieve prior imaging exams, labs and pathology reports. Display for MD review, verify orders, review chart to incorporate relevant clinical information.

Intra-Service Clinical Labor Activities: In addition to acquiring the images for the base procedure, the cardiac sonographer will explain all the elements of the echocardiogram which include the Doppler.

In conjunction with the acquisition of a sequence of real-time tomographic images of cardiac structure and dynamics digitally recorded, spectral Doppler is performed (by means of pulsed and/or continuous wave techniques). Digitally recorded flow velocity data are acquired. This includes: pressure gradients, stenotic valve areas, quantitation of regurgitation (regurgitant volume, fraction, and effective orifice area), global left ventricular systolic performance, right ventricular systolic pressure and diastolic function. Sonographic findings are analyzed throughout the course of the examination to ensure that sufficient data is provided to the physician to direct patient management and render a final diagnosis.

Post-Service Clinical Labor Activities: Documentation

CPT Code: 93320, 93321, 93325
Specialty Society(s) ACC, ASE

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor: 93321 Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List separately in addition to codes for echocardiographic imaging)

Global Period: ZZZ Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee: A joint RUC advisory committee of members from ACC and ASE reviewed and amended the current PE inputs in light of the completed surveys.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: 93321 is an existing code and was used as the reference. Since 93321 is an add-on code, 93306 is also referenced to demonstrate what a complete procedure looks like.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time: N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence: 10 minutes of equipment time is recommended on line 70. This seems to have been mistakenly left out in the past.

5. Please describe in detail the clinical activities of your staff:
Pre-Service Clinical Labor Activities: Retrieve prior imaging exams, labs and pathology reports. Display for MD review, verify orders, review chart to incorporate relevant clinical information.

Intra-Service Clinical Labor Activities: In addition to acquiring the images for the base procedure, the cardiac sonographer will explain all the elements of the echocardiogram which include the Doppler.

In conjunction with the acquisition of a sequence of real-time tomographic images of cardiac structure and dynamics digitally recorded, spectral Doppler is performed (by means of pulsed and/or continuous wave techniques). Digitally recorded flow velocity data are acquired. This may include one or more of the following: pressure gradients, stenotic valve areas, quantitation of regurgitation (regurgitant volume, fraction, and effective orifice area), global left ventricular systolic performance, right ventricular systolic pressure, and/or diastolic function. Sonographic findings are analyzed throughout the course of the examination to ensure that sufficient data is provided to the physician to direct patient management and render a final diagnosis.

Post-Service Clinical Labor Activities: Documentation

CPT Code: 93320, 93321, 93325
Specialty Society(s) ACC, ASE

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor: 93325 Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)

Global Period: ZZZ Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee: A joint RUC advisory committee of members from ACC and ASE reviewed and amended the current PE inputs in light of the completed surveys.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: 93325 is an existing code and was used as the reference. Since 93325 is an add-on code, 93306 is also referenced to demonstrate what a complete procedure looks like.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time: N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence: 11 minutes of time is recommended on lines 70, 72, and 73. These pieces of equipment are used during both the data acquisition and data processing steps.

5. Please describe in detail the clinical activities of your staff:
Pre-Service Clinical Labor Activities: Retrieve prior imaging exams, labs and pathology reports. Display for MD review, verify orders, review chart to incorporate relevant clinical information.

Intra-Service Clinical Labor Activities: In addition to acquiring the images for the base procedure, the cardiac sonographer will explain all the elements of the echocardiogram which include the Doppler.

In conjunction with the acquisition of a sequence of real-time tomographic images of cardiac structure and dynamics digitally recorded, color Doppler is performed. Digitally recorded color flow images are acquired. Assessment of the presence and severity of valve regurgitation, assessment of flow acceleration proximal to the regurgitant valve, assessment of flow acceleration within vessels and assessment of shunts and fistulae are all performed. Sonographic findings are analyzed throughout the course of the examination to ensure that sufficient data is provided to the physician to direct patient management and render a final diagnosis.

Post-Service Clinical Labor Activities: Documentation

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1				REFERENCE CODE		REFERENCE CODE		dation		REFERENCE CODE				REFERENCE CODE			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**93306**		**93320**		**93320**		**93321**		**93321**		**93325**		**93325**	
3	**Meeting Date: January 2014 Tab: 30 Specialty: cardiology**	**CMS Code**	**Staff Type**	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List		Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)		Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)	
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**																
6	**TOTAL CLINICAL LABOR TIME**			**72.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**8.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
8	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**60.0**	**0.0**	**19.0**	**0.0**	**19.0**	**0.0**	**10.0**	**0.0**	**10.0**	**0.0**	**11.0**	**0.0**	**11.0**	**0.0**
9	**TOTAL POST-SERV CLINICAL LABOR TIME**			**4.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
10	**PRE-SERVICE**																
11	**Start: Following visit when decision for surgery or procedure made**																
12	Complete pre-service diagnostic & referral forms																
13	Coordinate pre-surgery services																
14	Schedule space and equipment in facility																
15	Provide pre-service education/obtain consent																
16	Follow-up phone calls & prescriptions																
17	*Other Clinical Activity - *specify: Review prior echo studies*	L050A	Cardiac Sonographer	**3**													
18	*Other Clinical Activity - *specify: Precertification*	L037D	RN/LPN/MTA	**5**													
19	**End: When patient enters office/facility for surgery/procedure**																

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1				REFERENCE CODE		REFERENCE CODE		dation		REFERENCE CODE				REFERENCE CODE			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**93306**		**93320**		**93320**		**93321**		**93321**		**93325**		**93325**	
3	**Meeting Date: January 2014 Tab: 30 Specialty: cardiology**	**CMS Code**	**Staff Type**	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List		Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)		Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)	
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**																
20	**SERVICE PERIOD**																
21	**Start: When patient enters office/facility for surgery/procedure:**																
22	Greet patient, provide gowning, ensure appropriate medical records are available	L037D	RN/LPN/MTA	**3**													
23	Obtain vital signs	L037D	RN/LPN/MTA	**3**													
24	Provide pre-service education/obtain consent																
25	Prepare room, equipment, supplies	L050A	Cardiac Sonographer	**3**													
26	Setup scope (non facility setting only)																
27	Prepare and position patient/ monitor patient/ set up IV	L050A	Cardiac Sonographer	**3**													
28	Sedate/apply anesthesia																
29	*Other Clinical Activity - specify: Review charts (document clinical elements - patient history)	L037D	RN/LPN/MTA	**1**													
30	**Intra-service**																
31	Assist physician in performing procedure:	L050A	Cardiac Sonographer	**42**		**19**		**19**		**10**		**10**		**11**		**11**	
32	acquire images					14		14		8		8		9		9	
33	process data, measure & record prliminary findings					5		5		2		2		2		2	
34	Assist physician/moderate sedation (% of physician time)																

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1				REFERENCE CODE		REFERENCE CODE				REFERENCE CODE				REFERENCE CODE			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**93306**		**93320**		**93320**		**93321**		**93321**		**93325**		**93325**	
3	**Meeting Date: January 2014 Tab: 30 Specialty: cardiology**	**CMS Code**	**Staff Type**	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List		Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)		Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)	
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**																
35	**Post-Service**																
36	Monitor pt. following moderate sedation																
37	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)																
38	Clean room/equipment by physician staff	L050A	Cardiac Sonographer	**3**													
39	Clean Scope																
40	Clean Surgical Instrument Package																
41	Complete diagnostic forms, lab & X-ray requisitions																
42	Review/read X-ray, lab, and pathology reports																
43	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions																
44	*Other Clinical Activity - *specify:patient education, instruction, and counseling*	L050A	Cardiac Sonographer	**2**													
45	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)			**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**	
46	Dischrg mgmt (1.0 x 99238) (enter 12 min)			**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**	
47	Dischrg mgmt (1.0 x 99239) (enter 15 min)			**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**	
48	**End: Patient leaves office**																
49	**POST-SERVICE Period**																
50	**Start: Patient leaves office/facility**																
51	Conduct phone calls/call in prescriptions																
52	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**
53	99211 16 minutes		16														
54	99212 27 minutes		27														
55	99213 36 minutes		36														
56	99214 53 minutes		53														
57	99215 63 minutes		63														
58	**Total Office Visit Time**			**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
59	*Other Clinical Activity - *specify: QA documentation required or accreditation*	L050A	Cardiac Sonographer	**4**													
60	**End: with last office visit before end of global period**																

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1				REFERENCE CODE		REFERENCE CODE		dation		REFERENCE CODE				REFERENCE CODE			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**93306**		**93320**		**93320**		**93321**		**93321**		**93325**		**93325**	
3	**Meeting Date: January 2014 Tab: 30 Specialty: cardiology**	**CMS Code**	**Staff Type**	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List separately in addition		Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List separately in addition		Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)		Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)	
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**																
61	**MEDICAL SUPPLIES****	**CODE**	**UNIT**														
62	pack, minimum multi-specialty visit	SA048	pack	**1**													
63	electrode, ECG (single)	SD053	item	**3**													
64	drape, non-sterile, sheet 40in x 60in	SB006	item	**1**													
65	sanitizing cloth-wipe (surface, instruments, equipment)	SM022	item	**3**													
66	computer media, optical disk 128mb	SK015	item	**0.2**													
67	videotape, VHS	SK086	item	**0.2**													
68	ultrasound transmission gel	SJ062	ml	**180**													
69																	
70	**EQUIPMENT**	**CODE**															
71	computer, desktop with monitor	ED021		**63**		**14**		**0**				**0**		**9**		**0**	
72	video SVHS, VCR (medical grade)	ED034		**10**		**5**		**5**		**8**		**2**		**2**		**2**	
73	video printer, color (Sony	ED036		**63**		**14**		**0**		**10**		**0**		**9**		**0**	
74	stretcher	EF018		**63**		**14**		**14**		**10**		**8**		**9**		**9**	
75	ultrasound, echocardiography analyzer software (ProSolv)	EQ252		**10**		**5**				**8**				**2**			
76	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)	EQ253		**63**		**5**								**2**			
77	ultrasound, echocardiography w-4 transducers (Sequoia C256)	EQ254		**63**		**14**				**10**				**9**			
78	room, ultrasound, vascular	EL016						**14**				**8**				**9**	
79																	

AMA/Specialty Society RVS Update Committee Summary of Recommendations
High Volume Growth screen

January 2014

Continuous Glucose Monitoring

At the October 2013, meeting the Relativity Assessment Workgroup reviewed High Volume Growth Services where Medicare utilization increased by at least 100% from 2006 to 2011. The RUC requested that these services be surveyed for physician work and develop practice expense inputs for the January 2014 RUC meeting.

At the January 2014 RUC meeting the specialty societies requested and the RUC agreed to refer CPT codes 9520 and 95251 to the CPT Editorial Panel to revise these services. The specialty societies indicated that will request revisions to differentiate between "professional CGM" in which a patient wears the CGM device for 72 hours and "personal CGM" where the patient owns the CGM device and wears it for an extended period of time. **The RUC recommends that CPT codes 95250 and 95251 be referred to the CPT Editorial Panel for revision.**

CPT Code (•New)	**CPT Descriptor**	**Global Period**	**Work RVU Recommendation**
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording (Do not report 95250 more than once per month) (Do not report 95250 in conjunction with 99091)	XXX	Specialty Societies Request Referral to the CPT Editorial Panel
95251	interpretation and report (Do not report 95251 more than once per month) (Do not report 95251 in conjunction with 99091)	XXX	Specialty Societies Request Referral to the CPT Editorial Panel

November 15, 2013

Barbara Levy, MD
Chair, AMA/Specialty Society RVS Update Committee
American Medical Association
AMA Plaza
330 N. Wabash Avenue
Chicago, IL 60611-5885

Dear Dr. Levy,

The American Association of Clinical Endocrinologists, the Endocrine Society, and the American College of Physicians wish to request a delay in the survey of CPT codes related to continuous glucose monitoring (CGM; 95250 and 95251), which is currently due in January 2014, to allow submission of a Code Change Proposal to the CPT Editorial Panel prior to survey. The background for this request is provided below.

CPT code 95250 was established in 2002 and CPT code 95251 in 2006; both have been RUC-surveyed and approved for payment by CMS. Code 95251 was identified in 2013 as having failed a RUC screen for rapid growth (i.e. more than 100% growth in utilization over 5 years). An action plan requesting no further action regarding this code was submitted to the Relativity Assessment Workgroup in October 2013, but the Workgroup and the full RUC requested that code 95251 and the other code in the same family (95250) be surveyed for the Jan, 2014 RUC meeting. The specialty societies submitting this letter indicated a willingness to survey these codes.

During the preparation for survey, the specialty societies became aware of a serious problem with the current definition of the CPT codes: contacts with colleagues indicated that two separate services with widely disparate physician work, physician time, and practice expense were both being billed with these codes. Specifically, the original codes were established for a service (now termed “professional CGM”) in which a patient wears the CGM device (owned by the provider) for 72 hours, and the 3 days worth of blood glucose data points are subsequently analyzed by the physician.

In recent years, another service, termed “personal CGM” has grown in use: the patient owns the CGM device and wears it for an extended period of time. Under “personal CGM”, the patient makes adjustment in the treatment regimen based on the CGM results and the physician periodically analyzes the CGM data collected over an extended period. By contrast, under “professional CGM”, the data are collected over a much shorter period of time, patients are blinded to the results of the CGM while the data is collected, and patients generally do not make treatment changes during “professional CGM”.

These differences between “professional” and “personal” CGM translate into substantial differences in physician work and practice expense between the two services. For example, the patient instruction for “personal” CGM is much more extensive than for “professional” CGM, particularly the need to instruct the patient in how to adjust treatment based on the CGM data (not required for “professional” CGM). Similarly, the blood glucose data analyzed by the physician for a patient with “personal” CGM covers many more days than with “professional” CGM, and the data itself is more complicated to analyze because of the ongoing changes in treatment regimen during the collection of the data. However, the current CGM code descriptions do not distinguish between “professional” and “personal” CGM, and despite their substantial differences, both services are being reported with the current CGM codes since these are the only relevant codes available.

The purpose of the planned code change proposal is to modify the existing CGM codes to distinguish between “professional” and “personal” CGM, thereby providing a more accurate description of the services involved. In addition, this code change should facilitate the survey of CGM codes; surveying the existing family of two codes might well lead to ambiguity and inaccuracy because the codes as currently defined encompass widely disparate services.

Therefore, the undersigned specialty societies request permission to delay the survey of CPT codes 95250/95251, currently due in January, 2014, to allow presentation of a code change proposal to the May 2014 CPT editorial panel meeting (deadline for submission to the February CPT editorial meeting has passed). Following action by the CPT editorial panel, the codes would be surveyed for the following RUC meeting (Sept 2014).

Yours truly,

Allan R. Glass, M.D.
RUC Advisor
The Endocrine Society

MD

Mary Newman, M.D.
RUC Advisor
American College of Physicians

Howard Lando, M.D., FACP, FACE
RUC Advisor
American Association of Clinical Endocrinologists

AMA/Specialty Society RVS Update Committee Summary of Recommendations
High Volume Growth

January 2014

Electronic Analysis of Implanted Neurostimulator Pulse Generator System

At the October 2013, meeting the Relativity Assessment Workgroup reviewed High Volume Growth Services where Medicare utilization increased by at least 100% from 2006 to 2011. The RUC requested that these services be surveyed for physician work and develop practice expense inputs for the January 2014 RUC meeting.

95971 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
The RUC reviewed the survey results from 66 physicians for CPT code 95971 and determined that the current work RVU of 0.78 appropriately accounts for the work required to perform this service. The specialty societies indicated that the survey 25th percentile work RVU was 0.80, similar to the current value and there is not compelling evidence of a change in physician work at this time. The RUC agreed that 8 minutes pre-time, 20 minutes of intra-service time and 5 minutes immediate post-service time appropriately account for the work required to perform this service. The RUC compared code 95971 to key reference service 62370 *Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)* (work RVU = 0.90) and determined that 95971 requires slightly less physician work. For additional support, the RUC referenced MPC codes 95991 *Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular), includes electronic analysis of pump, when performed; requiring skill of a physician or other qualified health care professional* (work RVU = 0.77) and 93015 *Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with supervision, interpretation and report* (work RVU = 0.75). **The RUC recommends a work RVU of 0.78 for CPT code 95971.**

95972 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

The RUC reviewed the survey results from 60 physicians for CPT code 95972 and determined that the survey 25th percentile work RVU of 0.90 appropriately accounts for the work required to perform this service. The RUC agreed that 8 minutes pre-time, 23 minutes of intra-service time and 5 minutes immediate post-service time appropriately account for the work required to perform this service. The RUC compared code 95972 to key reference service 62370 *Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)* (work RVU = 0.90) and determined that both services require the same physician work. For additional support, the RUC referenced MPC code 74280 *Radiologic examination, colon; air contrast with specific high density barium, with or without glucagon* (work RVU = 0.99) and CPT code 95938 *Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs* (work RVU = 0.86). **The RUC recommends a work RVU of 0.90 for CPT code 95972.**

Commented [sc1]: Descriptor change request to be reviewed at CPT Editorial Board Meeting in May to delete "first hour" and replace with "up to one hour".

Refer to CPT

The RUC recommends that CPT codes 95971, 95972 and 95973 be referred to CPT to address the entire family regarding the time referenced in the CPT code descriptors. Specifically, the descriptor for code 95972 specifies "first hour" but survey results indicate that the majority of physicians reporting this code take less than 30 minutes. Per CPT rules, since the midpoint of the specified time is not exceeded, the code is not reportable in the majority of circumstances under which the service is performed.

Secondly for CY 2016, the relevant specialties should submit a code change proposal to more definitely address the concern and make the codes more consistent with current practice. The specialties anticipate two separate families; one for peripheral nerve root stimulators and another for spinal cord stimulators.

Work Neutrality

The RUC's recommendation for this family of codes will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

Practice Expense

The RUC recommends the direct practice expense inputs as modified by the Practice Expense Subcommittee.

CPT Code (●New)	CPT Descriptor	Global Period	Work RVU Recommendation
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming	XXX	0.78
95972	complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour	XXX	0.90

Commented [sc2]: Descriptor change request to be reviewed at CPT Editorial Board Meeting in May to delete "first hour" and replace with "up to one hour".

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:95971 Tracking Number

Original Specialty Recommended RVU: **0.78**
Presented Recommended RVU: **0.78**
RUC Recommended RVU: **0.78**

Global Period: XXX

CPT Descriptor: Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 56 year old patient with a condition that requires nerve stimulation returns for simple programming of the implanted neurostimulator pulse generator system where three or fewer of the parameters are adjusted.

Percentage of Survey Respondents who found Vignette to be Typical: 92%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 13%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 2%

Description of Pre-Service Work:
*Obtain and review records and previous history, laboratory studies and all imaging studies before the procedure;
*Evaluate voiding diary (if applicable)
*Verify appropriate programming equipment and patient's handheld programmer are available
* Place patient on table

Description of Intra-Service Work:
* Link programmer with patient programmer (hand held device)
* Interrogate patient’s neurostimulator device: review pre-set program settings by switching with hand held programmer between programs and record patient sensation
* Change the lead configuration
* Change amplitude until stimulation is felt, if appropriate then maintain that configuration; if inappropriate, then repeat until appropriate response is obtained.
*Three parameters are assessed and changed if necessary.
*Re-sync new program with patient held programmer

Description of Post-Service Work:
*Plan for replacement if necessary

*Discuss expectations with patient
*Re-educate patient on use of device
*Discuss follow up appointment
*Transfer data to hard copy, scan results into computer
*Dictate chart note
*Contact referring physician as appropriate
*Contact company for device malfunction/failure if appropriate

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014					
Presenter(s):	Thomas Turk, MD; Philip Wise, MD; Marc Lieb, MD; Karin Swartz, MD; Christopher Merifield, MD; George Hill, MD; David Krencik, MD					
Specialty(s):	American Urological Association, American Congress of Obstetricians and Gynecologists, American Society of Anesthesiologists, North American Spine Society, American Academy of Pain Medicine, International Spine Intervention Society					
CPT Code:	95971					
Sample Size:	2225	**Resp N:**	66	**Response:** 2.9 %		
Description of Sample:	Random					

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate		9.25	**15.00**	30.00	200.00
Survey RVW:	0.17	0.80	**0.98**	1.50	4.00
Pre-Service Evaluation Time:			**8.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	3.00	10.25	**20.00**	20.00	120.00

Immediate Post Service-Time:	**5.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

XXX Global Code

CPT Code:	95971	**Recommended Physician Work RVU: 0.78**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**8.00**	**0.00**	**8.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**20.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

XXX Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**5.00**	**0.00**	**5.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
62370	XXX	0.90	**RUC Time**

CPT Descriptor Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
95991	XXX	0.77	**RUC Time**	23,563

CPT Descriptor 1 Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular), includes electronic analysis of pump, when performed; requiring skill of a physician or other qualified health care professional

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
95251	XXX	0.85	**RUC Time**	29,201

CPT Descriptor 2 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 19 **% of respondents:** 28.7 **%**

TIME ESTIMATES (Median)

CPT Code: 95971	Key Reference CPT Code: 62370	Source of Time RUC Time

Median Pre-Service Time	8.00	7.00
Median Intra-Service Time	20.00	20.00
Median Immediate Post-service Time	5.00	10.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**33.00**	**37.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.63	3.47
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.74	3.47
Urgency of medical decision making	2.89	3.11
Technical Skill/Physical Effort (Mean)		
Technical skill required	3.84	3.68
Physical effort required	3.11	3.11
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	3.16	3.42
Outcome depends on the skill and judgment of physician	3.95	3.89
Estimated risk of malpractice suit with poor outcome	2.84	3.26

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	3.05	2.89
Intra-Service intensity/complexity	3.63	3.32
Post-Service intensity/complexity	2.79	2.68

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

CPT code 95971 was surveyed by six different specialty societies, American Urological Association, American Congress of Obstetricians and Gynecologists, American Society of Anesthesiologists, North American Spine Society, American Academy of Pain Medicine, International Spine Intervention Society. The surveys were sent to random 2,225 members of these specialty societies of which we received 66 responses at a 2.97% response rate. In 2013, 10,320 of these procedures were performed in the Medicare population so the number of responses to this survey meets the new RUC criteria of 30 respondents as the minimum survey sample size for this code.

A conference call of the participating specialty societies RUC advisors compared the current information in the RUC database and compared and reviewed the physician work survey results as well as practice expense. The survey median preservice time was eight minutes and the survey median postservice time was five minutes. The expert panel believes that these times are appropriate based on the description of preservice and postservice physician work outlined in this Summary of Recommendation.

The current intraservice time for 95971 is 20 minutes and the survey results came out exactly at 20 minutes as well. The current work RVU for 95971 is .78. The median survey RVU was .98 and the 25th percentile work RUV was .80. The involved specialty societies recommend that the current RVU of .78 be maintained.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 95971

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Urology How often? Sometimes

Specialty Interventional Pain How often? Sometimes

Specialty Anesthesia How often? Sometimes

Estimate the number of times this service might be provided nationally in a one-year period? 12900
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. Medicare X 125%

Specialty Urology Frequency 5032 Percentage 39.00 %

Specialty Interventional Pain Frequency 2012 Percentage 15.59 %

Specialty Anesthesia Frequency 1164 Percentage 9.02 %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 10,320 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. 10320

Specialty Urology Frequency 4026 Percentage 39.01 %

Specialty Interventional Pain Frequency 1610 Percentage 15.60 %

Specialty Anesthesia Frequency 931 Percentage 9.02 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Tests

BETOS Sub-classification:
Other tests

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 95971

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:95972 Tracking Number Original Specialty Recommended RVU: **0.90**

Presented Recommended RVU: **0.90**
Global Period: XXX RUC Recommended RVU: **0.90**

CPT Descriptor: Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 56 year old patient with a condition that requires nerve stimulation returns for complex programming of the implanted neurostimulator pulse generator system where four or more parameters are adjusted.

Percentage of Survey Respondents who found Vignette to be Typical: 93%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 11%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 3%

Description of Pre-Service Work:
*Obtain and review records and previous history, laboratory studies and all imaging studies before the procedure;
*Evaluate voiding diary (if applicable)
*Verify appropriate programming equipment and patient's handheld programmer are available
* Place patient on table

Description of Intra-Service Work:
* Link programmer with patient programmer (hand held device)
* Interrogate patient’s neurostimulator device: review pre-set program settings by switching with hand held programmer between programs and record patient sensation
* Change the lead configuration
* Change amplitude until stimulation is felt, if appropriate then maintain that configuration; if inappropriate, then repeat until appropriate response is obtained.
*Four or more parameters are assessed and changed if necessary.
*Re-sync new program with patient held programmer

Description of Post-Service Work:
*Plan for replacement if necessary

*Discuss expectations with patient
*Re-educate patient on use of device
*Discuss follow up appointment
*Transfer data to hard copy, scan results into computer
*Dictate chart note
*Contact referring physician as appropriate
*Contact company for device malfunction/failure if appropriate

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014					
Presenter(s):	Thomas Turk, MD; Philip Wise, MD; Marc Lieb, MD; Karin Swartz, MD; Christopher Merifield, MD; George Hill, MD; David Krencik, MD					
Specialty(s):	American Urological Association, American Congress of Obstetricians and Gynecologists, American Society of Anesthesiologists, North American Spine Society, American Academy of Pain Medicine, International Spine Intervention Society					
CPT Code:	95972					
Sample Size:	2227	**Resp N:**	60	**Response:** 2.6 %		
Description of Sample:	Random					

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate		3.75	**15.00**	31.50	200.00
Survey RVW:	0.48	0.90	**1.33**	1.71	4.50
Pre-Service Evaluation Time:			**10.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	5.00	15.00	**23.00**	30.00	180.00

Immediate Post Service-Time:	**8.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

XXX Global Code

CPT Code:	95972	**Recommended Physician Work RVU: 0.90**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**8.00**	**0.00**	**8.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**23.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

XXX Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**5.00**	**0.00**	**5.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
62370	XXX	0.90	**RUC Time**

CPT Descriptor Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
95251	XXX	0.85	**RUC Time**	29,201

CPT Descriptor 1 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
74280	XXX	0.99	**RUC Time**	24,130

CPT Descriptor 2 Radiologic examination, colon; air contrast with specific high density barium, with or without glucagon

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 16 **% of respondents:** 26.6 **%**

TIME ESTIMATES (Median)	**CPT Code: 95972**	**Key Reference CPT Code:** 62370	**Source of Time** RUC Time

Median Pre-Service Time	8.00	7.00
Median Intra-Service Time	23.00	20.00
Median Immediate Post-service Time	5.00	10.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**36.00**	**37.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.88	3.56
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.88	3.38
Urgency of medical decision making	3.25	3.31
Technical Skill/Physical Effort (Mean)		
Technical skill required	4.25	3.81
Physical effort required	3.50	3.19
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	3.50	3.50
Outcome depends on the skill and judgment of physician	4.44	3.94
Estimated risk of malpractice suit with poor outcome	3.25	3.50

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	3.56	3.31
Intra-Service intensity/complexity	4.19	3.63
Post-Service intensity/complexity	3.19	2.81

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

CPT code 95972 was surveyed by six different specialty societies, American Urological Association, American Congress of Obstetricians and Gynecologists, American Society of Anesthesiologists, North American Spine Society, American Academy of Pain Medicine, International Spine Intervention Society. The surveys were sent to random 2,227 members of these specialty societies of which we received 60 responses at a 2.69% response rate. In 2013, 63,743 of these procedures were performed in the Medicare population so the number of responses to this survey meets the new RUC criteria of 30 respondents as the minimum survey sample size for this code.

A conference call of the participating specialty societies RUC advisors compared the current information in the RUC database and compared and reviewed the physician work survey results as well as practice expense. The current intraservice time for 95972 is 60 minutes and the survey results indicated that the intraservice time was decreased to 23 minutes. The current work RVU for 95972 is 1.50. The median survey RVU was 1.33 and the 25th percentile work RUV was .90. The involved specialty societies recommend that the 25th percentile RVU of .90 be assigned to 95972 given the decrease in the intraservice time.

The survey median preservice time was ten minutes and the survey median postservice time was eight minutes. The expert panel believes that these times are appropriate based on the description of preservice and postservice physician work outlined in this Summary of Recommendation.

As a result of the survey, the specialty societies noted that the CPT code descriptor is no longer accurate for "first hour" given the decrease in intraservice time to 23 minutes. It would be appropriate to ask for code descriptor editorial change to "first 30 minutes" from the "first hour" to the CPT Editorial Panel.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 95972

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Urology How often? Sometimes

Specialty Interventional Pain Mgt How often? Sometimes

Specialty Anesthesia How often? Sometimes

Estimate the number of times this service might be provided nationally in a one-year period? 76678
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. Medicare X 125%

Specialty Urology Frequency 25498 Percentage 33.25 %

Specialty Interventinal Pain Mgt Frequency 13895 Percentage 18.12 %

Specialty Anesthesia Frequency 10334 Percentage 13.47 %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 63,743 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. Taken from the RUC database

Specialty Urology Frequency 20398 Percentage 32.00 %

Specialty Interventional Pain Mgt Frequency 11116 Percentage 17.43 %

Specialty Anesthesia Frequency 8267 Percentage 12.96 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Tests

BETOS Sub-classification:
Other tests

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 95972

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

SS Rec Summary

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
12	**ISSUE:**	**Electronic Analysis of Implanted Neurostimulator Pulse Generator System**																		
13	**TAB:**	**32**																		
14						**RVW**					**Total**	**PRE-TIME**			**INTRA-TIME**					**IMMD**
15	**Source**	**CPT**	**DESC**	**Resp**	**IWPUT**	**MIN**	**25th**	**MED**	**75th**	**MAX**	**Time**	**EVAL**	**POSIT**	**SDW**	**MIN**	**25th**	**MED**	**75th**	**MAX**	**POST**
16	REF	62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)		-0.004			0.90			64.00	7.00					20.00			37.00
17	CURRENT	95971			0.032			0.78			26.00	3.00					20.00			3.00
18	SVY	95971		66	0.034	0.17	0.80	0.98	1.50	4.00	33.00	8.00			3.00	10.25	20.00	20.00	120.00	5.00
19	REC	95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming	66	0.024			0.78			33.00	8.00					20.00			5.00
20																				
21																				
22	REF	62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)		-0.004			0.90			64.00	7.00					20.00			37.00
23	CURRENT	95972			0.022			1.50			68.00	3.00					60.00			5.00
24	SVY	95972		60	0.042	0.48	0.90	1.33	1.71	4.50	40.00	10.00			5.00	15.00	22.50	30.00	180.00	7.50
25	REC	95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour	60	0.026			0.90			36.00	8.00					23.00			5.00

Breakdown of Specialty Responses for Tab 32 CPT Codes 95971 and 95972
Electronic analysis of Implanted Neurostimulator Pulse Generator System

	95971	95972
Specialty Society	# Respondents	# Respondents
Total	**66**	**60**
American Society of Anesthesiologists	2	2
American Academy of Pain Medicine	6	5
North American Spine Society	0	0
International Spine Intervention Soceity	3	3
American Urological Association	13	13
American Congress of Obstetricians and Gynecologists*	42	37

*This survey was conducted with the American Urogynecologic Society, a subspecialty under ACOG. The subspecialty consists of gynecologists and urologists who specialize in female pelvic medicine and reconstructive surgery (FPMRS) who can be members of either ACOG or AUA. The respondents consisted of 25 gynecologists and 17 urologists for 95971 and 22 gynecologists and 15 urologists for 95972.

CPT Code: 95971

Specialty Society('s) American Urological Association, American Congress of Obstetricians and Gynecologists, American Society of Anesthesiologists, North American Spine Society, American Academy of Pain Medicine, International Spine Intervention Society

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:

95971 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming

Global Period: xxx Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee: RUC Advisors from each specialty society involved in this survey process reviewed the practice expense recommendations and approved them.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: These codes are being revised so we are using 95971 as our reference code.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Visit prior to procedure:
Provide pre-service education and obtain consent from patient

Day of Procedure – Pre-Service
Greet the patient
Provide gown
Ensure appropriate medical records are available
Obtain three vitals (BP, weight and temperature)
Prepare room, equipment and supplies

Intra-Service Clinical Labor Activities:

Assist physician in programming the neurostimulation system

Post-Service Clinical Labor Activities:

Clean the room and equipment
Provide follow up information to patient.
Patient education/teaching as appropriate based upon the visit
Confers with the MD verbally for any last minute instructions for patient.
Next appointment is set up for patient while checking out.

Next day after patient leaves the office, calls patient to verify if the new programming is working.

CPT Code: 95972

Specialty Society('s) American Urological Association, American Congress of Obstetricians and Gynecologists, American Society of Anesthesiologists, North American Spine Society, American Academy of Pain Medicine, International Spine Intervention Society

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:

95972 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

Global Period: xxx Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee: RUC Advisors from each specialty society involved in this survey process reviewed the practice expense recommendations and approved them.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: These codes are being revised so we are using 95972 as our reference code.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Visit prior to procedure:
Provide pre-service education and obtain consent from patient

Day of Procedure – Pre-Service
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Intra-Service Clinical Labor Activities:

Assist physician in programming the neurostimulation system

Post-Service Clinical Labor Activities:

Clean the room and equipment
Provide follow up information to patient.
Patient education/teaching as appropriate based upon the visit
Confers with the MD verbally for any last minute instructions for patient.
Next appointment is set up for patient while checking out.

Next day after patient leaves the office, calls patient to verify if the new programming is working.

	A	B	C	D	E	F	G
1				EXISTING INPUTS			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**CPT Code # 95971**		**CPT Code # 95971**	
3	**Meeting Date: January 2014 Tab: 32 Specialty: American Urological Association, American Congress of Obstetricians and Gynecologists, American Society of Anesthesiologists, North American Spine Society, American Academy of Pain Medicine, International Spine Intervention Society**	**CMS Code**	**Staff Type**	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve,		Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve,	
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**			**XXX**		**XXX**	
6	**TOTAL CLINICAL LABOR TIME**	**L037D**	**RN/LPN/MTA**	**27.0**	**0.0**	**30.0**	**0.0**
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**	**L037D**	**RN/LPN/MTA**	**0.0**	**0.0**	**0.0**	**0.0**
8	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**	**L037D**	**RN/LPN/MTA**	**27.0**	**0.0**	**27.0**	**0.0**
9	**TOTAL POST-SERV CLINICAL LABOR TIME**	**L037D**	**RN/LPN/MTA**	**0.0**	**0.0**	**3.0**	**0.0**
10	**PRE-SERVICE**						
11	**Start: Following visit when decision for surgery or procedure made**						
12	Complete pre-service diagnostic & referral forms			**0**			
13	Coordinate pre-surgery services			**0**			
14	Schedule space and equipment in facility			**0**			
15	Provide pre-service education/obtain consent						
16	Follow-up phone calls & prescriptions			**0**			
17	*Other Clinical Activity - *specify:*						
18	**End: When patient enters office/facility for surgery/procedure**						
19	**SERVICE PERIOD**						
20	**Start: When patient enters office/facility for surgery/procedure:**						
21	Greet patient, provide gowning, ensure appropriate medical records are available			**6**		**3**	
22	Obtain vital signs			**3**		**3**	
23	Provide pre-service education/obtain consent						
24	Prepare room, equipment, supplies			**2**		**2**	
25	Prepare and position patient/monitor patient/set up IV			**2**		**2**	
26	**Intra-service**						
27	Assist physician in performing procedure			**14**		**14**	
28	Assist physician/moderate sedation (66 % of physician time)						
29	**Post-Service**						
30	Clean room/equipment by physician staff					**3**	
31	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)			**n/a**		**n/a**	
32	Dischrg mgmt (1.0 x 99238) (enter 12 min)			**n/a**		**n/a**	
33	Dischrg mgmt (1.0 x 99239) (enter 15 min)			**n/a**		**n/a**	
34	**End: Patient leaves office**						
35	**POST-SERVICE Period**						
36	**Start: Patient leaves office/facility**						
37	Conduct phone calls/call in prescriptions					**3**	
38	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**
39	99211 16 minutes		16				
40	99212 27 minutes		27				
41	99213 36 minutes		36				
42	99214 53 minutes		53				
43	99215 63 minutes		63				
44	**Total Office Visit Time**			**0.0**	**0.0**	**0.0**	**0.0**
45	*Other Clinical Activity - *specify:*						
46	**End: with last office visit before end of global period**						
47	**MEDICAL SUPPLIES****	**CODE**	**UNIT**				
48	pack, minimum multi-specialty visit	SA048	pack	**1**		**1**	
49							
50	**EQUIPMENT**	**CODE**					
51	Programmer, neurostimulator (w-printer)	EQ209		**27**		**27**	
52	Table, exam	EF023		**27**		**27**	
53							
54							
55							

	A	B	C	D	E	F	G	H
1				EXISTING INPUTS				
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**CPT Code # 95972**		**CPT Code # 95972**		
3	**Meeting Date: January 2014 Tab: 32 Specialty: American Urological Association, American Congress of Obstetricians and Gynecologists, American Society of Anesthesiologists, North American Spine Society, American Academy of Pain Medicine, International Spine Intervention Society**	**CMS Code**	**Staff Type**	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour		Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour		
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	
5	**GLOBAL PERIOD**			**XXX**		**XXX**		
6	**TOTAL CLINICAL LABOR TIME**	**L037D**	**RN/LPN/MTA**	**44.0**	**0.0**	**31.0**	**0.0**	
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**	**L037D**	**RN/LPN/MTA**	**0.0**	**0.0**	**0.0**	**0.0**	
8	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**	**L037D**	**RN/LPN/MTA**	**44.0**	**0.0**	**28.0**	**0.0**	
9	**TOTAL POST-SERV CLINICAL LABOR TIME**	**L037D**	**RN/LPN/MTA**	**0.0**	**0.0**	**3.0**	**0.0**	
10	**PRE-SERVICE**							
11	**Start: Following visit when decision for surgery or procedure made**							
12	Complete pre-service diagnostic & referral forms			**0**		**0**		
13	Coordinate pre-surgery services			**0**		**0**		
14	Schedule space and equipment in facility			**0**		**0**		
15	Provide pre-service education/obtain consent			**0**		**0**		
16	Follow-up phone calls & prescriptions			**0**		**0**		
17	*Other Clinical Activity - *specify:*							
18	**End: When patient enters office/facility for surgery/procedure**							
19	**SERVICE PERIOD**							
20	**Start: When patient enters office/facility for surgery/procedure:**							
21	Greet patient, provide gowning, ensure appropriate medical records are available					**3**		
22	Obtain vital signs					**3**		
23	Provide pre-service education/obtain consent							
24	Prepare room, equipment, supplies			**2**		**2**		
25	Prepare and position patient			**2**		**2**		
26	**Intra-service**							
27	Assist physician in performing procedure (2/3 of physician time)			**40**		**15**		
28	Assist physician/moderate sedation (66% of physician time)							
29	**Post-Service**							
30	Clean room/equipment by physician staff					**3**		
31	Clean Scope							
32	Clean Surgical Instrument Package							
33	Complete diagnostic forms, lab & X-ray requisitions							
34	Review/read X-ray, lab, and pathology reports							
35	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions							
36	*Other Clinical Activity - *specify:*							
37	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)			**n/a**		**n/a**		
38	Dischrg mgmt (1.0 x 99238) (enter 12 min)			**n/a**		**n/a**		
39	Dischrg mgmt (1.0 x 99239) (enter 15 min)			**n/a**		**n/a**		
40	**End: Patient leaves office**							
41	**POST-SERVICE Period**							
42	**Start: Patient leaves office/facility**							
43	Conduct phone calls/call in prescriptions					**3**		
44	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**	
45	99211 16 minutes		16					
46	99212 27 minutes		27					
47	99213 36 minutes		36					
48	99214 53 minutes		53					
49	99215 63 minutes		63					
50	**Total Office Visit Time**			**0.0**	**0.0**	**0.0**	**0.0**	
51	*Other Clinical Activity - *specify:*							
52	**End: with last office visit before end of global period**							
53	**MEDICAL SUPPLIES****	**CODE**	**UNIT**					
54	pack, minimum multi-specialty visit	SA048	pack	**1**				
55								
56	**EQUIPMENT**	**CODE**						
57	Programmer, neurostimulator (w-printer)	EQ209		**44**		**28**		
58	Table, exam	EF023		**44**		**28**		
59								
60								
61								

AMA/Specialty Society RVS Update Committee Summary of Recommendations
CMS/Other-Utilization over 250,000 screen
January 2014

Hyperbaric Oxygen Therapy

The Relativity Assessment Workgroup identified these services through the CMS/Other Source – Utilization over 250,000 screen. In October 2013, the RUC noted that these services were never RUC reviewed but are frequently reported. The RUC recommended that these services be surveyed for physician work and develop direct practice expense inputs for the January 2014 RUC meeting.

The RUC reviewed CPT code 99183 *Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session* and determined that a work RVU of 2.11 appropriately accounts for the work required to perform this service. The specialty societies indicated that the survey conducted had methodological problems due to improper communication to possible survey respondents and therefore should not be used to recommend a work value for the surveyed code. The specialty societies recommended and the RUC agreed that a direct crosswalk to MPC code 90937 *Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription* (work RVU = 2.11) and 10 minutes pre-service, 40 minutes intra-service and 10 minutes immediate post-service time is appropriate. Both 99183 and 90937 describe a complicated patient that is previously known to the provider, is receiving a treatment familiar to the patient that lasts for several hours and in which a provider with specialty training for these particular services spends some but not all time bedside to the patient during the treatment. The specialty societies confirmed and the RUC agreed that 10 minutes of pre-service time is necessary for each session as the physician must review the patients interaction with multiple physicians, review changes in medication, review recent surgery or potential for surgery, assess the current blood sugar which is the main risk for hypoglycemic seizures while in the chamber and decide whether dietary supplements are necessary and ultimately responsible for conducting safety check list each session. **The RUC recommends a work RVU of 2.11 for CPT code 99183.**

Work Neutrality
The RUC's recommendation for these codes will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

Practice Expense
The RUC recommends the direct practice expense inputs as modified by the Practice Expense Subcommittee.

CPT Code (•New)	CPT Descriptor	Global Period	Work RVU Recommendation
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session	XXX	2.11

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:99183 Tracking Number Original Specialty Recommended RVU: **2.34**
Presented Recommended RVU: **2.11**
Global Period: XXX RUC Recommended RVU: **2.11**

CPT Descriptor: Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A patient with longstanding hypertension and insulin dependent diabetes develops a deep to bone foot ulcer that has not improved after 30 consecutive days of standard wound therapy. The patient is referred for adjunctive hyperbaric oxygen therapy.

Percentage of Survey Respondents who found Vignette to be Typical: 82%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: Review labs and vital signs, with special attention to pulmonary function, blood pressure and blood sugar level. Examine patient to confirm that physical findings have not changed, new medications are appropriate in the hyperbaric environment and update H&P. Review procedure with patient, including risks and complications. Confirm orders for treatment time, dose and pressure limits and advise on nutritional supplements, as needed. Monitor/assist with patient positioning and grounding and ensure that the patient is cleared and appropriate for therapy. Verify that checklist has been completed and assure the availability of cardiac life support for emergency.

Description of Intra-Service Work: Physician provides supervision during the hyperbaric oxygen therapy session and is immediately available should a complication occur. The physician directs patient clearing maneuvers with chamber-side decision to continue to prescribed depth. The physician will intervene as needed to address potential complications (order air break). If indicated, physician will advise patient of the termination of the treatment, monitoring for symptoms during ascent.

Description of Post-Service Work: Reassess patient blood sugar level and blood pressure. Evaluate patient for barotrauma (ears, sinuses, lungs) or other complications. Discuss need for off-loading weight from affected limb as well as glycemic control. Discharge patient with instructions for possible barotrauma symptomatic relief; if necessary, prescribe appropriate medications. Determine next treatment date and any change in treatment protocol due to complications. Dictate progress notes for medical record, with copy to referring physician. Consult with referring physician(s), as needed, regarding concurrent wound care as well as insulin (medication) management.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014				
Presenter(s):	Ethan Booker, MD, Helen Gelly, MD, Charles Mabry, MD, Mary Newman, MD				
Specialty(s):	ACEP, ACP, ACS, UHMS				
CPT Code:	99183				
Sample Size:	932	**Resp N:**	103	**Response:** 11.0 %	
Description of Sample:	Random from membership rosters				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	20.00	200.00	**500.00**	1000.00	3533.00
Survey RVW:	0.75	2.00	**2.49**	2.83	5.00
Pre-Service Evaluation Time:			**10.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	5.00	15.00	**45.00**	110.00	150.00

Immediate Post Service-Time:	**10.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

XXX Global Code

CPT Code:	99183	**Recommended Physician Work RVU: 2.11**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**10.00**	**0.00**	**10.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**40.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

XXX Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**10.00**	**0.00**	**10.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
99204	XXX	2.43	**RUC Time**

CPT Descriptor Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
99215	XXX	2.11	**RUC Time**	9,577,362

CPT Descriptor 1 Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
99204	XXX	2.43	**RUC Time**	8,853,265

CPT Descriptor 2 Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 24 **% of respondents:** 23.3 **%**

TIME ESTIMATES (Median)	**CPT Code: 99183**	**Key Reference CPT Code:** 99204	**Source of Time RUC Time**
Median Pre-Service Time	10.00	5.00	
Median Intra-Service Time	40.00	30.00	
Median Immediate Post-service Time	10.00	10.00	
Median Critical Care Time	0.0	0.00	
Median Other Hospital Visit Time	0.0	0.00	
Median Discharge Day Management Time	0.0	0.00	
Median Office Visit Time	0.0	0.00	
Prolonged Services Time	0.0	0.00	
Median Subsequent Observation Care Time	0.0	0.00	
Median Total Time	**60.00**	**45.00**	
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	4.08	4.29
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.33	3.67
Urgency of medical decision making	2.63	4.08
Technical Skill/Physical Effort (Mean)		
Technical skill required	3.79	3.50
Physical effort required	3.83	3.46
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	2.88	4.04
Outcome depends on the skill and judgment of physician	4.04	3.25
Estimated risk of malpractice suit with poor outcome	3.46	2.83

INTENSITY/COMPLEXITY MEASURES	CPT Code	Reference Service 1
Time Segments (Mean)		
Pre-Service intensity/complexity	3.67	3.92
Intra-Service intensity/complexity	3.75	3.54
Post-Service intensity/complexity	3.71	3.00

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 99183

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty general surgery — How often? Commonly

Specialty internal medicine — How often? Commonly

Specialty emergency medicine — How often? Commonly

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. National data is not available

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period?
559,800 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. RUC database

Specialty general surgery	Frequency 110105	Percentage 19.66 %
Specialty internal medicine	Frequency 94232	Percentage 16.83 %
Specialty emergency medicine	Frequency 72267	Percentage 12.90 %

Do many physicians perform this service across the United States? No

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 99183

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

ISSUE: Hyperbaric Oxygen Therapy

TAB: 33

					RVW					Tota	PRE	INTRA				POST-	EXPERIENCE			
SOURCE	CPT	DESC	Resp	IWPUT	MIN	25th	MED	75th	MAX	Time	PRE	MIN	25th	MED	75th	MAX	P-SD	MIN	25th	MED	75th	MAX
KEY REF	99204	Office or other outpatient visit for th	24	0.070			2.43			45	5			30			10					
CMS/OTH	99183	Physician or other qualified health		0.040			2.34			59				59								
SURVEY	99183	Physician or other qualified health	103	0.045	0.75	2.00	2.49	2.83	5.00	65	10	5	15	45	110	150	10	20	200	500	1000	3533
REC	99183	MAINTAIN CURRENT VALUE		0.042			2.11			60	10			40			10					

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:
Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session

Global Period: XXX **Meeting Date**: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

A consensus panel of society Advisors and physicians familiar with this service reviewed database practice expense details and found the inputs to be significantly understated for the typical office treatment.

2. You must provide reference code(s) for comparison on your spreadsheet. If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison. You must provide an explanation for the selection of reference codes. Reference Code Rationale:

Code 99183 details were used as a reference. The PE spreadsheet includes the recommendations developed by CMS staff in 2004 (no specialty took interest in this code during the PEAC review years) and the final CMS approved details published in 2005.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:

Position the patient and moving the patient into the chamber takes more than the standard two minutes. Please see explanation of work for that line item below.

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:

Information that we have from 2004 indicate that CMS staff (Pam West) submitted a spreadsheet that included 135 minutes of "assist physician" time for a respiratory therapist and 24 minutes of blended staff for other activities. Final CMS determination resulted in 60 minutes for respiratory therapist assist time and 22 minutes of blended staff time for other activities. There is no information regarding these changes and we believe the reduction in clinical staff time was incorrect. The typical "dive" takes 120 minutes and the standard of practice for patient safety is 100% attendance and availability of clinical staff. In the event of an emergency, there needs to be one staff per patient available to carry out emergency procedures. Attendence throughout the therapy is important as an emergency can occur at any moment. In addition, no time was allocated for cleaning the air break masks/lines or the inside of the chamber, both of which are mandatory and time consuming. Each activity listed below is required for every patient and for every procedure.

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities (prior to patient arrival at site):

Activity	Staff	Min	Discussion
Follow-up phone calls & prescriptions	**RN/LPN/MTA**	**3**	Phone call to confirm appointment and health status of patient.

Service Clinical Labor Activities (from patient arrival until patient departure):

Activity	Staff	Min	Discussion
Greet patient, provide gowning, ensure appropriate medical records are available	**RN/LPN/MTA**	**3**	standard time
Obtain vital signs	**RN/LPN/MTA**	**5**	BP, pulse, resp rate, temp, weight
***Other Clinical:** blood glucose, food/H2O, blood glucose recheck	**RN/LPN/MTA**	**3**	blood glucose, food/H2O, blood glucose recheck
Provide pre-service education/obtain consent	**RN/Resp Therapist**	**3**	Education/reinforcement regarding prohibited activities during treatment and instruction/practice regarding various valsalva techniques.
Prepare room, equipment, supplies	**RN/LPN/MTA**	**2**	Note, this is for pre/post holding room and testing supplies and food; not for the chamber room.
Prepare and position patient/ monitor patient/ set up IV	**RN/Resp Therapist**	**4**	Lower chamber gurney to lowest point for ease of patient transfer. Assist / situate patient comfortably on chamber gurney. Wrap external orthotic devices with padding to protect chamber. Raise patient gurney with assistance to appropriate height, mate to chamber rails. Lock in place. Test ground strap with meter to ensure proper ground per regulation, attach to patient wrist. Slide patient / gurney into chamber and lock in place. Unlock gurney frame from rails and pull away to ready for door closure. Close and check seal of door. Time out to confirm patient is ready to proceed.
***Other Clinical:**Turn on chamber operating panel, check communications with patient and adjust volumes, prepare chamber operating settings per physician order	**RN/Resp Therapist**	**5**	Turn on chamber operating panel, check communications with patient and adjust volumes, prepare chamber operating settings per physician order
Assist physician in performing procedure	**RN/Resp Therapist**	**120**	**Descent:** monitor patient for equalization issues, communicate frequently with patient to ensure their safety and well-being. **At treatment pressure**: Monitor patient throughout treatment. Shift patient to air break mask every 30 min to lessen potential for oxygen toxicity per protocol. Prepare patient verbally for ascent back to normal pressure. **Ascent:** Monitor patient for equalization issues, communicate frequently with patient to ensure their safety and well-being.

Activity	Staff	Min	Discussion
Monitor pt. following service/check tubes, monitors, drains not related to moderate sedation	**RN/Resp Therapist**	**5**	Unlock chamber door. Unmate gurney from chamber rails and slide gurney out of chamber. Lower gurney with assistance to allow for ease of patient transfer. Continually assess patient for any abnormal clinical issues. Engage in conversation.
***Other Clinical:** post-service blood glucose, food/H2O, blood glucose recheck	**RN/LPN/MTA**	**5**	Post-service blood glucose, food/H2O, blood glucose recheck
Clean room/equipment by physician staff	**RN/LPN/MTA**	**3**	Clean room used for patient pre/post holding and blood glucose testing area; not cleaning chamber and equipment
***Other Clinical:** clean air mask and tubes, clean inside of chamber	**RN/LPN/MTA**	**10**	Clean/sterilize mask/tubes (similar to cleaning endoscope). Wash the chamber cylinder with 100% cotton, lint free cloth moistened with a mild detergent solution. Rinse and dry with 100% cotton, lint free, water moistened cloth. Place all linens in appropriate laudry receptacles. Clean positioning pads.
Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	**RN/Resp Therapist**	**3**	Reinforce home instructions on activities and diet. Schedule next session.

Post-Service Clinical Labor Activities (after patient departure):

N/A

	A	B	C	D	E	F	G	H	I	J
1				staff 2004		Final Rule 2005		Jan-2014 Rec		
2	*Please note: If a supply has a purchase price of $100 or			99183		99183		99183		
3	REVISED 1-30-14 Meeting Date: January 2014 Tab: 33 Specialty: ACS, ACEP, ACP, UHMS	CMS Code	Staff Type	Physician or other qualified health care professional attendance and supervision of		Physician or other qualified health care professional attendance and supervision of		Physician or other qualified health care professional attendance and supervision of		EQUIPMENT TIME CALCULATION
4	LOCATION			Office	Facility	Office	Facility	Office	Facility	
5	GLOBAL PERIOD			XXX	XXX	XXX	XXX	XXX	XXX	
6	TOTAL CLINICAL LABOR TIME			159	0	82	0	107	0	145
7	TOTAL PRE-SERV CLINICAL LABOR TIME	L037D	RN/LPN/MTA	0	0	0	0	0	0	
8	TOTAL SERVICE PERIOD CLINICAL LABOR TIME	L037D	RN/LPN/MTA	24	0	22	0	29	0	
9	TOTAL SERVICE PERIOD CLINICAL LABOR TIME	L042B	Resp Therapist	135	0	60	0	0	0	
10	TOTAL SERVICE PERIOD CLINICAL LABOR TIME	L047C	RN/Resp Therapist	0	0	0	0	78	0	
11	TOTAL POST-SERV CLINICAL LABOR TIME			0	0	0	0	0	0	
12	PRE-SERVICE									
21	SERVICE PERIOD									
22	Start: When patient enters office/facility for surgery/procedure:									
23	Greet patient, provide gowning, ensure appropriate medical records are available	L037D	RN/LPN/MTA	3		3		3		
24	Obtain vital signs	L037D	RN/LPN/MTA	5		5		5		
25	***Other Clinical:** blood glucose, food/H2O, blood glucose recheck	L037D	RN/LPN/MTA					3		
26	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA	2		2				
27	Provide pre-service education/obtain consent Mandatory safety check/review prior to dive	L047C	RN/Resp Therapist					3		
28	Prepare room, equipment, supplies	L037D	RN/LPN/MTA	2				2		
30	Prepare and position patient/ monitor patient/ set up IV	L047C	RN/Resp Therapist	4		4		4		4
32	***Other Clinical:**Turn on chamber operating panel, check communications with patient and adjust volumes, prepare chamber operating settings per physician order	L047C	RN/Resp Therapist					3		3
33	Intra-service									
34	Assist physician in performing procedure	L042B	Resp Therapist	135		60				
35	Assist physician in performing procedure - 1/2 time	L047C	RN/Resp Therapist					60		
36	*TOTAL "DIVE" TIME = 120 MIN FOR PURPOSE OF EQUIPMENT TIME, BUT ASSIST IS 1/2 = 60 MIN*							*120*		120
37	Post-Service									
39	Monitor pt. following service/check tubes, monitors, drains not related to moderate sedation	L047C	RN/Resp Therapist					5		5
40	***Other Clinical:** post-service blood glucose, food/H2O, blood glucose recheck	L037D	RN/LPN/MTA	5		5		3		
41	Clean room/equipment by physician staff	L037D	RN/LPN/MTA	3		3		3		3
42	***Other Clinical:** clean air mask and tubes, clean inside of chamber	L037D	RN/LPN/MTA					10		10
47	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	L047C	RN/Resp Therapist					3		
51	End: Patient leaves office									
52	POST-SERVICE Period									
64	DISPOSABLE MEDICAL SUPPLIES**	CODE	UNIT							
65	cover, thermometer probe	SB004	item					1		
66	gloves, non-sterile *one pair pre dive and one pair post dive for blood testing*	SB022	pair					2		
67	specula tips, otoscope	SM025	item	2		2		2		
68	test strip, glucose (blood test)	SJ069	item					4		
69	urinal	SJ063	item	1		1		1		
70	gas, air	SD077	cu ft	187		187		30		
71	gas, oxygen	SD084	liter	180		180		47,600		
72	disinfectant, surface (Envirocide, Sanizide)	SM013	oz	1		1		1		
73	lint-free cloth	SL088	item					4		
74	pack, cleaning and disinfecting, endoscope	SA042	pack					0.5		
75	denture cup	SJ016	item	1		1		0		
76	EQUIPMENT (over $500)	CODE								
77	~~hyperbaric chamber~~ HBOT (hyperbaric oxygen therapy) monochamber, incl gurney and integrated grounding assembly	EQ131		82		82		145		
78	pulse oximeter w-printer	EQ211		82		82		0		
79	HBOT air break breathing apparatus demand system (hoses, masks, penetrator and demand valve)	NEW						145		

AMA/Specialty Society RVS Update Committee Summary of Recommendations
Identified as part of the New Technology/New Services screen

January 2014

Lapraroscopic Hysterectomy

These services were identified through the New Technology/New Services List in April 2007. In October 2013, the Relativity Assessment Workgroup noted there may have been diffusion in technology for this service and requests that the specialty society's survey physician work and review practice expense at the January 2014 meeting.

The specialty societies requested and the RUC agreed that these services be postponed to April 2014 RUC meeting. The specialty societies determined that the vignettes to be included in the survey were not typical. The vignettes will be revised to reflect typical patients for these procedures. **The RUC recommends that these services be postponed and surveyed for physician work and develop direct practice expense inputs for the April 2014 RUC meeting.**

CPT Code (•New)	CPT Descriptor	Global Period	Work RVU Recommendation
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less;	090	Postponed to April 2014 RUC meeting
58542	with removal of tube(s) and/or ovary(s) (Do not report 58541, 58542 in conjunction with 49320, 57000, 57180, 57410, 58140-58146, 58545, 58546, 58561, 58661, 58670, 58671)	090	Postponed to April 2014 RUC meeting

58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g;	090	Postponed to April 2014 RUC meeting
58544	with removal of tube(s) and/or ovary(s) (Do not report 58543-58544 in conjunction with 49320, 57000, 57180, 57410, 58140-58146, 58545, 58546, 58561, 58661, 58670, 58671)	090	Postponed to April 2014 RUC meeting
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less;	090	Postponed to April 2014 RUC meeting
58571	with removal of tube(s) and/or ovary(s)	090	Postponed to April 2014 RUC meeting
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	090	Postponed to April 2014 RUC meeting
58573	with removal of tube(s) and/or ovary(s)	090	Postponed to April 2014 RUC meeting

The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

January 7, 2014

Barbara Levy, MD
Chair, RUC
8655 W Higgins Road
Chicago, IL 60631

Re: Tab 24 Laparoscopic Hysterectomy

Dear Dr. Levy:

ACOG recently conducted RUC physician work surveys for the eight laparoscopic hysterectomy procedures (CPT Codes 58541-4 and 58570-3). We are scheduled to present the tab at the upcoming RUC meeting in Phoenix.

We would like permission to defer this tab to the April RUC meeting. Our survey respondents did not feel our vignettes were typical. We proposed changing the vignettes to the research subcommittee prior to conducting these surveys. However, the subcommittee did not feel our proposed changes were appropriate at that time. We continue to believe the vignettes should be updated to reflect typical patients for these procedures. We will work with the research subcommittee to come to consensus on appropriate vignettes for these surveys.

We apologize for the delay but feel strongly that we need to conduct new surveys. Thank you for your consideration of our request. If you have any questions, please contact me at ghill@nashvillefertility.com.

Respectfully,

George A Hill, MD
ACOG RUC Advisor

cc: Sherry Smith
Anne Diamond

AMA
AMERICAN MEDICAL ASSOCIATION

ama-assn.org
t (312) 464-5000

March 21, 2014

Marilyn B. Tavenner
Administrator
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: HCPAC Recommendations

Dear Ms. Tavenner:

The RUC Health Care Professionals Advisory Committee (HCPAC) Review Board submits the enclosed recommendation to the Centers for Medicare and Medicaid Services (CMS). On January 30, 2014, the HCPAC reviewed the strapping procedure CPT codes 29200, 29240, 29260, 29280, 29520 and 29530, which were identified by the Relativity Assessment Workgroup through the High Volume Growth screen.

The RUC and HCPAC are fully committed to this ongoing effort to improve relativity in the work, practice expense, and professional liability insurance values. The HCPAC appreciates the opportunity to provide recommendations related to the 2015 Medicare Physician Payment Schedule. If you have any questions regarding this submission, please contact Susan Clark via (202) 789-7495 or Susan.Clark@ama-assn.org at the AMA for clarification regarding these recommendations.

Sincerely,

Barbara Levy, MD
RUC Chair

William J. Mangold, Jr, MD
HCPAC Chair

Anthony Hamm, DC
HCPAC Co-Chair

cc: HCPAC Participants
Kathy Bryant
Jessica Bruton
Edith Hambrick, MD
Ryan Howe
Steve Phurrough, MD

Attachments

HCPAC Recommendations for Existing Codes

CPT Code	Descriptor	HCPAC Recommendation	High Volume Growth
29260	Strapping; elbow or wrist	0.39	X
29240	Strapping; shoulder (eg, Velpeau)	0.39	X
29520	Strapping; hip	0.39	X
29280	Strapping; hand or finger	0.39	X
29200	Strapping; thorax	0.39	X
29530	Strapping; knee	0.39	X

March 2014

AMA/Specialty Society RVS Update Committee Summary of Recommendations
High Volume Growth screen

January 2014

Strapping Procedures

At the October 2013 meeting, the Relativity Assessment Workgroup reviewed High Volume Growth Services where Medicare utilization increased by at least 100% from 2006 to 2011. The RUC requested that these services be surveyed for physician work and develop practice expense inputs.

Strapping Procedures (29200, 29240, 29260, 29280, 29520, 29530)
The American Physical Therapy Association (APTA) surveyed all six strapping services and the American Occupational Therapy Association (AOTA) participated only in the survey of CPT code 29280.

The HCPAC reviewed the survey results for codes strapping codes 29200, 29240, 29260, 29280, 29520 and 29530 and determined that all six strapping codes require the same work, time, intensity and complexity to perform as the key reference service 29540 *Strapping; ankle and/or foot* (work RVU = 0.39 and 7 minutes pre-service 9 minutes intra-service and 2 minutes immediate post-service time). The survey respondents indicated 0.40 median work RVUs and 0.39 work RVUs for the 25th percentile for all codes except CPT code 29520, in which survey respondents indicated a median work RVU of 0.49 and 25th percentile work RVU of 0.40. The HCPAC recommends crosswalking all six strapping codes to key reference service code 29540. The HCPAC noted that these services are typically reported with therapeutic services 97110 *Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility* (work RVU = 0.45) or 97140 *Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes* (work RVU = 0.43). APTA and AOTA noted the pre-service and post-service times have been reduced and do not include any overlap in the work of the health care professional pre- and post-time associated with codes 97110 and 97140. APTA and AOTA also noted that 97110 and 97140 are "always therapy" services and if the strapping codes are reported with 97110 and 97140, the "always therapy" codes will be reduced under the MPPR. The HCPAC determined that the recommended times are appropriate and do not include any overlap in services.

The HCPAC also referenced CPT codes 29584 *Application of multi-layer compression system; upper arm, forearm, hand, and fingers* (work RVU = 0.35 and 18 minutes total time) and 97116 *Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)* (work RVU = 0.40 and 15 minutes total time) to support the recommended work RVU of 0.39.

The HCPAC recommends a work RVU of 0.39 and 7 minutes pre-service, 9 minutes intra-service and 2 minutes immediate post-service time for CPT codes 29200, 29240, 29260, 29280, 29520 and 29530.

Work Neutrality
The RUC's recommendation for these codes will result in an overall work savings that should be redistributed back to the Medicare conversion factor.

Practice Expense
The PE Subcommittee adjusted the direct practice expense inputs to be consistent with the current standards, including adjusting the reference code 29540 and code 29550 which was not included in the review of work. The PE Subcommittee noted that the splint medical supplies are not reported separately, therefore were appropriately added. The inches of tape differ among the strapping codes because different lengths are necessary depending on which body site is being addressed. **The HCPAC accepted the direct practice expense inputs as modified by the PE Subcommittee.**

CPT Code (•New)	Tracking Number	CPT Descriptor	Global Period	Work RVU Recommendation
29200		Strapping; thorax (29220 has been deleted) (To report low back strapping, use 29799)	000	0.39
29240		shoulder (eg, Velpeau)	000	0.39
29260		elbow or wrist	000	0.39
29280		hand or finger	000	0.39
29520		Strapping; hip	000	0.39

29530		knee	000	0.39

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:29200 Tracking Number

Original Specialty Recommended RVU: **0.40**
Presented Recommended RVU: **0.40**
RUC Recommended RVU: **0.39**

Global Period: 000

CPT Descriptor: Strapping; Thorax

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 62 year-old female office worker presents with osteoporosis and a recent diagnosis of thoracic compression fractures T11, T12. She has a mildly kyphotic posture and reports significant pain in her mid-back.

Percentage of Survey Respondents who found Vignette to be Typical: 77%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: A history is obtained. Examination of skin integrity, sensory integrity, cardiopulmonary status and range of motion of shoulder/thoracic complex are performed. Treatment options are reviewed and communication occurs with the patient (and/or the patient's family) to explain the procedure, including a discussion of possible risks and complications.

Description of Intra-Service Work: The patient is placed in an upright sitting position with her shoulder, scapulae and thoracic spine held in a comfortable position. The strapping material is sized and cut into an upright bridge shape. Low irritant material is applied under the strapping material to reduce the likelihood of skin irritation with rigid strapping material over the top. Starting at the patient’s shoulders and drawing the straps down toward the outer rib cage, manually correcting the kyphonic posture if needed, the lower extensions are trimmed and attached to the outer ribcage.

Description of Post-Service Work: Instructions are provided for care, complications, and activity. Treatment note and any correspondence with referring physicians are completed.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014				
Presenter(s):	Stephen Levine, PT, DPT, MSHA				
Specialty(s):	American Physical Therapy Association				
CPT Code:	29200				
Sample Size:	985	**Resp N:**	22	**Response:** 2.2 %	
Description of Sample:	Randomly chosen from APTA's database of physical therapists in outpatient practice.				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	0.00	**3.00**	12.00	50.00
Survey RVW:	0.25	0.39	**0.40**	0.64	5.00
Pre-Service Evaluation Time:			**22.50**		
Pre-Service Positioning Time:			**5.00**		
Pre-Service Scrub, Dress, Wait Time:			**4.00**		
Intra-Service Time:	0.00	10.00	**15.00**	18.75	45.00

Immediate Post Service-Time:	**5.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

5 - NF Procedure without sedation/anesthesia care

CPT Code:	29200	**Recommended Physician Work RVU: 0.39**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**7.00**	**7.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**1.00**	**-1.00**
Intra-Service Time:		**9.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

7A Local/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**2.00**	**16.00**	**-14.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
29540	000	0.39	**RUC Time**

CPT Descriptor Strapping; ankle and or foot

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97110	XXX	0.45	**RUC Time**	44,238,381

CPT Descriptor 1 Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97124	XXX	0.35	**RUC Time**	806,701

CPT Descriptor 2 Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 14 **% of respondents:** 63.6 **%**

TIME ESTIMATES (Median)	**CPT Code: 29200**	**Key Reference CPT Code:** 29540	**Source of Time** **RUC Time**

Median Pre-Service Time	7.00	7.00
Median Intra-Service Time	9.00	9.00
Median Immediate Post-service Time	2.00	2.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**18.00**	**18.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)		**(of those that selected Key Reference code)**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.79	3.71
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.36	3.36
Urgency of medical decision making	3.07	3.07
Technical Skill/Physical Effort (Mean)		
Technical skill required	4.14	4.14
Physical effort required	2.86	2.86
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	2.07	2.07
Outcome depends on the skill and judgment of physician	3.86	3.93
Estimated risk of malpractice suit with poor outcome	2.00	1.93

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	3.07	3.00
Intra-Service intensity/complexity	3.71	3.86
Post-Service intensity/complexity	2.50	2.50

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The strapping codes being presented were identified in a CMS/RAW edit for increased utilization. Four codes were identified, however there were two additional codes in the family that were Harvard value and thus six codes are being brought forward. There are a total of eight codes in the family and the two remaining codes in the family (strapping, ankle and strapping, toes, 29540 and 29550, respectively) were presented to the RUC in 2010.

While the six codes were surveyed by APTA, it was recognized that code 29280, strapping, hand/finger, was primarily reported by Occupational Therapists (22% OT, 13% PT). APTA made contact with AOTA who provided a random sample of OTs to include in the survey for this one code. APTA was the primary provider of the other five codes.

The survey codes were distributed to a random selection of PTs obtained from APTA's membership data base of PTs in private practice. Three groups of 1,000 PTs were randomly selected and each group received two codes to review in order to address the survey burden and hopefully increase response rates. As noted, AOTA added approximately 200 randomly selected OTs for the survey of 29280 (strapping, hand/finger).

APTA convened an expert panel to review the results of the surveys. The most striking feature was the four of the surveyed codes returned similar results for the median work value (codes 29200, 29240, 29260, 29530). These values were in line with the reference code chosen, 29540 (strapping, ankle). A fifth code (29520, strapping, hip), which also used the reference code 29540 (strapping, ankle) gave very slightly different numbers for the work value.

The sixth code 29280, strapping, hand/finger had different results. The primary reference code selected by 9 of the respondents was 29126 (Splints, dynamic) and this may have impacted the results. Please note however, that 8 respondents used the 29540 (strapping, ankle) as the primary reference code, ie, the reference code selected in each of the other five codes surveyed. An analysis of the respondents to this survey did not show any significant differences in survey data based on whether an OT or a PT completed the survey.

APTA shared the results of this survey with the AOTA for their thoughts and the development of a joint recommendation to present to the HCPAC. Based on the sample sized obtained and the strong correlation of the codes to the reference code 29540 (strapping, ankle), the recommendation is for the work values for all six of the codes to be the same as the reference code and the SOR were thus completed.

In contrast to the work values, the pre, intra and post service minutes had a wide range of values. A clinical review by the expert panel was unable to support this range of minutes and the expert panel believes that the appropriate minutes should be those used in the primary reference code 29540 (strapping, ankle). These minutes are 7 pre, 9, intra and 2 post.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and

accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) Previously reported as the same code

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty APTA How often? Sometimes

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 30000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 15617
If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment
Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Musculoskeletal

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 29200

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:29240 Tracking Number

Original Specialty Recommended RVU: **0.40**
Presented Recommended RVU: **0.40**
RUC Recommended RVU: **0.39**

Global Period: 000

CPT Descriptor: Strapping; Shoulder

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 43-year-old male presents with a history of shoulder dislocations in spite of consistently performing prescribed exercises. Due to a recent dislocation he is considering surgery as the relocated shoulder is painful with movement and the patient reports that it feels unstable.

Percentage of Survey Respondents who found Vignette to be Typical: 100%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: A history is obtained. Examination of skin integrity, sensory integrity, and range of motion of shoulder/thoracic complex are assessed due to the instability. Treatment options are reviewed and communication occurs with the patient (and/or the patient's family) to explain the procedure, including a discussion of possible risks and complications.

Description of Intra-Service Work: The patient is placed in a standing position with his shoulder, scapulae and thoracic spine placed in a comfortable position with his hand on his hip. Low irritant material is applied under the strapping material to reduce the likelihood of skin irritation with rigid strapping material over the top. Anchors are applied over the shoulder and around contracted biceps, followed by straight line strapping along the side of the arm up to the anchor, and completed with shoulder crossing strapping. The amount of strapping for each direction is dependent of the amount of stability required to stabilize and upload the painful structures.

Description of Post-Service Work: Instructions are provided for care, complications, and activity. Treatment note and any correspondence with referring physicians are completed.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014				
Presenter(s):	Stephen Levine, PT, DPT, MSHA				
Specialty(s):	American Physical Therapy Association				
CPT Code:	29240				
Sample Size:	988	**Resp N:**	23	**Response:** 2.3 %	
Description of Sample:	Randomly chosen from APTA's database of physical therapists in outpatient practice.				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	2.00	**5.00**	17.50	50.00
Survey RVW:	0.25	0.39	**0.40**	0.58	10.00
Pre-Service Evaluation Time:			**20.00**		
Pre-Service Positioning Time:			**5.00**		
Pre-Service Scrub, Dress, Wait Time:			**5.00**		
Intra-Service Time:	0.00	12.50	**15.00**	20.00	60.00

Immediate Post Service-Time:	**7.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

5 - NF Procedure without sedation/anesthesia care

CPT Code:	29240	**Recommended Physician Work RVU: 0.39**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**7.00**	**7.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**1.00**	**-1.00**
Intra-Service Time:		**9.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

7A Local/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**2.00**	**16.00**	**-14.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
29540	000	0.39	**RUC Time**

CPT Descriptor Strapping; ankle and or foot

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97110	XXX	0.45	**RUC Time**	44,238,381

CPT Descriptor 1 Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97124	XXX	0.35	**RUC Time**	806,701

CPT Descriptor 2 Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 12 **% of respondents:** 52.1 **%**

TIME ESTIMATES (Median)	**CPT Code: 29240**	**Key Reference CPT Code:** 29540	**Source of Time** **RUC Time**

Median Pre-Service Time	7.00	7.00
Median Intra-Service Time	9.00	9.00
Median Immediate Post-service Time	2.00	2.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**18.00**	**18.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)		**(of those that selected Key Reference code)**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.83	3.50
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.42	3.17
Urgency of medical decision making	2.50	2.17
Technical Skill/Physical Effort (Mean)		
Technical skill required	4.25	4.00
Physical effort required	3.17	3.08
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	1.58	1.67
Outcome depends on the skill and judgment of physician	4.00	3.92
Estimated risk of malpractice suit with poor outcome	1.58	1.50

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	3.00	3.00
Intra-Service intensity/complexity	4.08	3.83
Post-Service intensity/complexity	2.75	2.67

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The strapping codes being presented were identified in a CMS/RAW edit for increased utilization. Four codes were identified, however there were two additional codes in the family that were Harvard value and thus six codes are being brought forward. There are a total of eight codes in the family and the two remaining codes in the family (strapping, ankle and strapping, toes, 29540 and 29550, respectively) were presented to the RUC in 2010.

While the six codes were surveyed by APTA, it was recognized that code 29280, strapping, hand/finger, was primarily reported by Occupational Therapists (22% OT, 13% PT). APTA made contact with AOTA who provided a random sample of OTs to include in the survey for this one code. APTA was the primary provider of the other five codes.

The survey codes were distributed to a random selection of PTs obtained from APTA's membership data base of PTs in private practice. Three groups of 1,000 PTs were randomly selected and each group received two codes to review in order to address the survey burden and hopefully increase response rates. As noted, AOTA added approximately 200 randomly selected OTs for the survey of 29280 (strapping, hand/finger).

APTA convened an expert panel to review the results of the surveys. The most striking feature was the four of the surveyed codes returned similar results for the median work value (codes 29200, 29240, 29260, 29530). These values were in line with the reference code chosen, 29540 (strapping, ankle). A fifth code (29520, strapping, hip), which also used the reference code 29540 (strapping, ankle) gave very slightly different numbers for the work value.

The sixth code 29280, strapping, hand/finger had different results. The primary reference code selected by 9 of the respondents was 29126 (Splints, dynamic) and this may have impacted the results. Please note however, that 8 respondents used the 29540 (strapping, ankle) as the primary reference code, ie, the reference code selected in each of the other five codes surveyed. An analysis of the respondents to this survey did not show any significant differences in survey data based on whether an OT or a PT completed the survey.

APTA shared the results of this survey with the AOTA for their thoughts and the development of a joint recommendation to present to the HCPAC. Based on the sample sized obtained and the strong correlation of the codes to the reference code 29540 (strapping, ankle), the recommendation is for the work values for all six of the codes to be the same as the reference code and the SOR were thus completed.

In contrast to the work values, the pre, intra and post service minutes had a wide range of values. A clinical review by the expert panel was unable to support this range of minutes and the expert panel believes that the appropriate minutes should be those used in the primary reference code 29540 (strapping, ankle). These minutes are 7 pre, 9, intra and 2 post.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and

accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) Previously reported as the same code

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty APTA How often? Sometimes

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 60000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period?
30,531 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty.
Please explain the rationale for this estimate.

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment
Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Musculoskeletal

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 29240

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:29260 Tracking Number

Original Specialty Recommended RVU: **0.40**
Presented Recommended RVU: **0.40**
RUC Recommended RVU: **0.39**

Global Period: 000

CPT Descriptor: Strapping; Elbow or Wrist

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 27-year-old female presents with a sprained wrist that's painful and accompanied by swelling from what she reports is from a severe twisting of her wrist while moving boxes late the night before. A fracture has been ruled out.

Percentage of Survey Respondents who found Vignette to be Typical: 71%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: A history is obtained. Examination of skin integrity, sensory integrity, and level of edema are assessed in the effected wrist. Treatment options are reviewed and communication occurs with the patient (and/or the patient's family) to explain the procedure, including a discussion of possible risks and complications.

Description of Intra-Service Work: The patient is placed in a sitting position with her hand positioned on a flat surface, palm down, with her fingers extended and relaxed. Low irritant material is applied under the strapping material to reduce the likelihood of skin irritation with rigid strapping material over the top. The strapping material is anchored by wrapping it twice over the metacarpal-phalangeal joints, then wrapping to the forearm.

Description of Post-Service Work: Instructions are provided for care, complications, and activity. Treatment note and any correspondence with referring physicians are completed.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014		
Presenter(s):	Stephen Levine, PT, DPT, MSHA		
Specialty(s):	American Physical Therapy Association		
CPT Code:	29260		
Sample Size:	969	**Resp N:** 14	**Response:** 1.4 %
Description of Sample:	Randomly chosen from APTA's database of physical therapists in outpatient practice.		

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	0.00	**3.00**	15.00	30.00
Survey RVW:	0.25	0.39	**0.40**	0.64	4.00
Pre-Service Evaluation Time:			**6.50**		
Pre-Service Positioning Time:			**2.50**		
Pre-Service Scrub, Dress, Wait Time:			**0.50**		
Intra-Service Time:	0.00	10.00	**15.00**	18.75	45.00

Immediate Post Service-Time:	**5.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

5 - NF Procedure without sedation/anesthesia care

CPT Code:	29260	**Recommended Physician Work RVU: 0.39**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**7.00**	**7.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**1.00**	**-1.00**
Intra-Service Time:		**9.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

7A Local/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**2.00**	**16.00**	**-14.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
29540	000	0.39	**RUC Time**

CPT Descriptor Strapping; ankle and or foot

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97110	XXX	0.45	**RUC Time**	44,238,381

CPT Descriptor 1 Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97124	XXX	0.35	**RUC Time**	806,701

CPT Descriptor 2 Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 8 **% of respondents:** 57.1 **%**

TIME ESTIMATES (Median)	**CPT Code: 29260**	**Key Reference CPT Code:** 29540	**Source of Time** **RUC Time**

Median Pre-Service Time	7.00	7.00
Median Intra-Service Time	9.00	9.00
Median Immediate Post-service Time	2.00	2.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**18.00**	**18.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.75	3.75
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	2.75	2.75
Urgency of medical decision making	2.13	2.13
Technical Skill/Physical Effort (Mean)		
Technical skill required	4.00	4.13
Physical effort required	2.63	2.63
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	2.13	2.13
Outcome depends on the skill and judgment of physician	4.13	4.13
Estimated risk of malpractice suit with poor outcome	2.00	1.88

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	2.25	2.25
Intra-Service intensity/complexity	3.50	3.50
Post-Service intensity/complexity	2.50	2.50

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The strapping codes being presented were identified in a CMS/RAW edit for increased utilization. Four codes were identified, however there were two additional codes in the family that were Harvard value and thus six codes are being brought forward. There are a total of eight codes in the family and the two remaining codes in the family (strapping, ankle and strapping, toes, 29540 and 29550, respectively) were presented to the RUC in 2010.

While the six codes were surveyed by APTA, it was recognized that code 29280, strapping, hand/finger, was primarily reported by Occupational Therapists (22% OT, 13% PT). APTA made contact with AOTA who provided a random sample of OTs to include in the survey for this one code. APTA was the primary provider of the other five codes.

The survey codes were distributed to a random selection of PTs obtained from APTA's membership data base of PTs in private practice. Three groups of 1,000 PTs were randomly selected and each group received two codes to review in order to address the survey burden and hopefully increase response rates. As noted, AOTA added approximately 200 randomly selected OTs for the survey of 29280 (strapping, hand/finger).

APTA convened an expert panel to review the results of the surveys. The most striking feature was the four of the surveyed codes returned similar results for the median work value (codes 29200, 29240, 29260, 29530). These values were in line with the reference code chosen, 29540 (strapping, ankle). A fifth code (29520, strapping, hip), which also used the reference code 29540 (strapping, ankle) gave very slightly different numbers for the work value.

The sixth code 29280, strapping, hand/finger had different results. The primary reference code selected by 9 of the respondents was 29126 (Splints, dynamic) and this may have impacted the results. Please note however, that 8 respondents used the 29540 (strapping, ankle) as the primary reference code, ie, the reference code selected in each of the other five codes surveyed. An analysis of the respondents to this survey did not show any significant differences in survey data based on whether an OT or a PT completed the survey.

APTA shared the results of this survey with the AOTA for their thoughts and the development of a joint recommendation to present to the HCPAC. Based on the sample sized obtained and the strong correlation of the codes to the reference code 29540 (strapping, ankle), the recommendation is for the work values for all six of the codes to be the same as the reference code and the SOR were thus completed.

In contrast to the work values, the pre, intra and post service minutes had a wide range of values. A clinical review by the expert panel was unable to support this range of minutes and the expert panel believes that the appropriate minutes should be those used in the primary reference code 29540 (strapping, ankle). These minutes are 7 pre, 9, intra and 2 post.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and

accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) Previously reported as the same code

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty APTA How often? Sometimes

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 15000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 7,840
If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment
Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Musculoskeletal

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 29260

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:29280 Tracking Number

Original Specialty Recommended RVU: **0.40**
Presented Recommended RVU: **0.40**
RUC Recommended RVU: **0.39**

Global Period: 000

CPT Descriptor: Strapping; Hand/finger

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 57-year-old male presents with a non-dislocated fracture of the medial phalange of the ring finger of the right hand. He presents with no other bony or skin injuries to the other fingers of the hand.

Percentage of Survey Respondents who found Vignette to be Typical: 70%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: A history is obtained. Examination of skin integrity, sensory integrity, and level of edema are assessed in the effected and adjacent fingers. Treatment options are reviewed and communication occurs with the patient (and/or the patient's family) to explain the procedure, including a discussion of possible risks and complications.

Description of Intra-Service Work: The patient is placed in a sitting position with his hand positioned on a flat surface, palm down, with his fingers extended and relaxed. A layer of absorbent material is placed between the two digits to be strapped. Low irritant material is applied under the strapping material to reduce the likelihood of skin irritation with rigid strapping material over the top. The strapping material is sized and wrapped around the ring and middle fingers (buddy wrapping) both distal and proximal to the fracture.

Description of Post-Service Work: Instructions are provided for care, complications, and activity. Treatment note and any correspondence with referring physicians are completed.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014				
Presenter(s):	Mary Foto, OT, FAOTA, CCM and Stephen Levine, PT, DPT, MSHA				
Specialty(s):	AOTA and APTA				
CPT Code:	29280				
Sample Size:	1172	**Resp N:**	24	**Response:** 2.0 %	
Description of Sample:	Randomly chosen from APTA's database of physical therapists in outpatient practice.				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	0.00	**2.50**	12.75	99.00
Survey RVW:	0.10	0.39	**0.64**	0.77	35.00
Pre-Service Evaluation Time:			**15.00**		
Pre-Service Positioning Time:			**4.50**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	0.00	10.00	**15.00**	26.25	45.00

Immediate Post Service-Time:	**10.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

5 - NF Procedure without sedation/anesthesia care

CPT Code:	29280	**Recommended Physician Work RVU: 0.39**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**7.00**	**7.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**1.00**	**-1.00**
Intra-Service Time:		**9.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

7A Local/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**2.00**	**16.00**	**-14.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
29540	000	0.39	**RUC Time**

CPT Descriptor Strapping; ankle or foot

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97110	XXX	0.45	**RUC Time**	44,238,381

CPT Descriptor 1 Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97124	XXX	0.35	**RUC Time**	806,701

CPT Descriptor 2 Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)

Other Reference CPT Code	Global	Work RVU	Time Source

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 8 **% of respondents:** 33.3 **%**

TIME ESTIMATES (Median)	**CPT Code: 29280**	**Key Reference CPT Code:** 29540	**Source of Time** **RUC Time**

Median Pre-Service Time	7.00	7.00
Median Intra-Service Time	9.00	9.00
Median Immediate Post-service Time	2.00	2.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**18.00**	**18.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)		**(of those that selected Key Reference code)**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.67	3.67
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.56	3.56
Urgency of medical decision making	3.33	3.22
Technical Skill/Physical Effort (Mean)		
Technical skill required	4.56	4.67
Physical effort required	2.89	3.11
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	2.44	2.33
Outcome depends on the skill and judgment of physician	4.11	4.11
Estimated risk of malpractice suit with poor outcome	2.56	2.33

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	2.67	2.56
Intra-Service intensity/complexity	4.33	4.22
Post-Service intensity/complexity	2.67	2.78

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The strapping codes being presented were identified in a CMS/RAW edit for increased utilization. Four codes were identified, however there were two additional codes in the family that were Harvard value and thus six codes are being brought forward. There are a total of eight codes in the family and the two remaining codes in the family (strapping, ankle and strapping, toes, 29540 and 29550, respectively) were presented to the RUC in 2010.

While the six codes were surveyed by APTA, it was recognized that code 29280, strapping, hand/finger, was primarily reported by Occupational Therapists (22% OT, 13% PT). APTA made contact with AOTA who provided a random sample of OTs to include in the survey for this one code. APTA was the primary provider of the other five codes.

The survey codes were distributed to a random selection of PTs obtained from APTA's membership data base of PTs in private practice. Three groups of 1,000 PTs were randomly selected and each group received two codes to review in order to address the survey burden and hopefully increase response rates. As noted, AOTA added approximately 200 randomly selected OTs for the survey of 29280 (strapping, hand/finger).

APTA convened an expert panel to review the results of the surveys. The most striking feature was the four of the surveyed codes returned similar results for the median work value (codes 29200, 29240, 29260, 29530). These values were in line with the reference code chosen, 29540 (strapping, ankle). A fifth code (29520, strapping, hip), which also used the reference code 29540 (strapping, ankle) gave very slightly different numbers for the work value.

The sixth code 29280, strapping, hand/finger had different results. The primary reference code selected by 9 of the respondents was 29126 (Splints, dynamic) and this may have impacted the results. Please note however, that 8 respondents used the 29540 (strapping, ankle) as the primary reference code, ie, the reference code selected in each of the other five codes surveyed. An analysis of the respondents to this survey did not show any significant differences in survey data based on whether an OT or a PT completed the survey.

APTA shared the results of this survey with the AOTA for their thoughts and the development of a joint recommendation to present to the HCPAC. Based on the sample sized obtained and the strong correlation of the codes to the reference code 29540 (strapping, ankle), the recommendation is for the work values for all six of the codes to be the same as the reference code and the SOR were thus completed.

In contrast to the work values, the pre, intra and post service minutes had a wide range of values. A clinical review by the expert panel was unable to support this range of minutes and the expert panel believes that the appropriate minutes should be those used in the primary reference code 29540 (strapping, ankle). These minutes are 7 pre, 9, intra and 2 post.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions:

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and

accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) Previously reported as the same code

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty AOTA How often? Sometimes

Specialty APTA How often? Sometimes

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 15000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. Percentages are based on the percentages that made claims through Medicare.

Specialty AOTA Frequency 3304 Percentage 22.02 %

Specialty APTA Frequency 1916 Percentage 12.77 %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 7,595
If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. Percentages come from the RUC database from Claims data from 2013

Specialty AOTA Frequency 1673 Percentage 22.02 %

Specialty APTA Frequency 969 Percentage 12.75 %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment
Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Musculoskeletal

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 29280

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:29520 Tracking Number

Original Specialty Recommended RVU: **0.40**
Presented Recommended RVU: **0.40**
RUC Recommended RVU: **0.39**

Global Period: 000

CPT Descriptor: Strapping; Hip

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 27-year-old female presents with a 3 year history of anterior-medial groin pain and a recent diagnosis of an acetabular labral tear. Excessive hip adduction and internal rotation on the involved side reproduce her symptoms.

Percentage of Survey Respondents who found Vignette to be Typical: 78%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: A history is obtained. Examination of skin integrity, sensory integrity, and range of motion of the effected limb are assessed. Treatment options are reviewed and communication occurs with the patient (and/or the patient's family) to explain the procedure, including a discussion of possible risks and complications.

Description of Intra-Service Work: With the patient standing wearing a sturdy tank top, a hip-strapping device is applied. This involves multiple steps of applying and adjusting strapping rotating around the hip laterally and using spiral strapping along the thigh and hip joint and anchoring to the tank top. Additional strapping for hip abduction includes adjustment of a split strap which is attached to thigh cuffs to resist hip adduction while applying vertical lower trunk compression. Final adjustments must be made to ensure the position of the acetabulum and restriction of adduction and internal rotation.

Description of Post-Service Work: Instructions are provided for care, complications, and activity. Treatment note and any correspondence with referring physicians are completed.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014				
Presenter(s):	Stephen Levine, PT, DPT, MSHA				
Specialty(s):	American Physical Therapy Association				
CPT Code:	29520				
Sample Size:	976	**Resp N:**	9	**Response:** 0.9 %	
Description of Sample:	Randomly chosen from APTA's database of physical therapists in outpatient practice.				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	2.00	**3.00**	10.00	10.00
Survey RVW:	0.35	0.40	**0.49**	0.51	10.00
Pre-Service Evaluation Time:			**20.00**		
Pre-Service Positioning Time:			**5.00**		
Pre-Service Scrub, Dress, Wait Time:			**1.00**		
Intra-Service Time:	0.00	7.00	**8.00**	12.00	30.00

Immediate Post Service-Time:	**5.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

5 - NF Procedure without sedation/anesthesia care

CPT Code:	29520	**Recommended Physician Work RVU: 0.39**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**7.00**	**7.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**1.00**	**-1.00**
Intra-Service Time:		**9.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

7A Local/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**2.00**	**16.00**	**-14.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
29540	000	0.39	**RUC Time**

CPT Descriptor Strapping; ankle and or foot

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97110	XXX	0.45	**RUC Time**	44,238,381

CPT Descriptor 1 Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97124	XXX	0.35	**RUC Time**	806,701

CPT Descriptor 2 Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 7 **% of respondents:** 77.7 **%**

TIME ESTIMATES (Median)	**CPT Code: 29520**	**Key Reference CPT Code:** 29540	**Source of Time** **RUC Time**

Median Pre-Service Time	7.00	7.00
Median Intra-Service Time	9.00	9.00
Median Immediate Post-service Time	2.00	2.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**18.00**	**18.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)		**(of those that selected Key Reference code)**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.71	3.43
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.14	2.86
Urgency of medical decision making	2.43	2.29
Technical Skill/Physical Effort (Mean)		
Technical skill required	3.86	3.43
Physical effort required	3.29	2.71
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	2.00	1.86
Outcome depends on the skill and judgment of physician	3.57	3.57
Estimated risk of malpractice suit with poor outcome	2.00	2.00

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	2.57	2.43
Intra-Service intensity/complexity	4.00	3.57
Post-Service intensity/complexity	2.71	2.57

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The strapping codes being presented were identified in a CMS/RAW edit for increased utilization. Four codes were identified, however there were two additional codes in the family that were Harvard value and thus six codes are being brought forward. There are a total of eight codes in the family and the two remaining codes in the family (strapping, ankle and strapping, toes, 29540 and 29550, respectively) were presented to the RUC in 2010.

While the six codes were surveyed by APTA, it was recognized that code 29280, strapping, hand/finger, was primarily reported by Occupational Therapists (22% OT, 13% PT). APTA made contact with AOTA who provided a random sample of OTs to include in the survey for this one code. APTA was the primary provider of the other five codes.

The survey codes were distributed to a random selection of PTs obtained from APTA's membership data base of PTs in private practice. Three groups of 1,000 PTs were randomly selected and each group received two codes to review in order to address the survey burden and hopefully increase response rates. As noted, AOTA added approximately 200 randomly selected OTs for the survey of 29280 (strapping, hand/finger).

APTA convened an expert panel to review the results of the surveys. The most striking feature was the four of the surveyed codes returned similar results for the median work value (codes 29200, 29240, 29260, 29530). These values were in line with the reference code chosen, 29540 (strapping, ankle). A fifth code (29520, strapping, hip), which also used the reference code 29540 (strapping, ankle) gave very slightly different numbers for the work value.

The sixth code 29280, strapping, hand/finger had different results. The primary reference code selected by 9 of the respondents was 29126 (Splints, dynamic) and this may have impacted the results. Please note however, that 8 respondents used the 29540 (strapping, ankle) as the primary reference code, ie, the reference code selected in each of the other five codes surveyed. An analysis of the respondents to this survey did not show any significant differences in survey data based on whether an OT or a PT completed the survey.

APTA shared the results of this survey with the AOTA for their thoughts and the development of a joint recommendation to present to the HCPAC. Based on the sample sized obtained and the strong correlation of the codes to the reference code 29540 (strapping, ankle), the recommendation is for the work values for all six of the codes to be the same as the reference code and the SOR were thus completed.

In contrast to the work values, the pre, intra and post service minutes had a wide range of values. A clinical review by the expert panel was unable to support this range of minutes and the expert panel believes that the appropriate minutes should be those used in the primary reference code 29540 (strapping, ankle). These minutes are 7 pre, 9, intra and 2 post.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and

accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) Previously reported as the same code

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty APTA How often? Sometimes

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 30000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 15,679 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? Yes

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Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Musculoskeletal

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 29520

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:29530 Tracking Number

Original Specialty Recommended RVU: **0.40**
Presented Recommended RVU: **0.40**
RUC Recommended RVU: **0.39**

Global Period: 000

CPT Descriptor: Strapping; Knee

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 16-year-old male presents with a sprained knee. He reports he twisted it while walking on an icy surface. His knee presents as warm with edema.

Percentage of Survey Respondents who found Vignette to be Typical: 78%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: A history is obtained. Examination of skin integrity, sensory integrity, and level of edema are assessed in the effected knee. Treatment options are reviewed and communication occurs with the patient (and/or the patient's family) to explain the procedure, including a discussion of possible risks and complications.

Description of Intra-Service Work: The patient is placed in a supine position with the knee at approximately a 30 degree angle. Low irritant material is applied under the strapping material to reduce the likelihood of skin irritation with rigid strapping material over the top. Anchors are applied gently to account for swelling around the extremity above and below the knee. Lateral crosses, lateral straight line, or medial straight lines crosses are applied to the anchors in a combination best suited to maintain an appropriate position of the knee joint.

Description of Post-Service Work: Instructions are provided for care, complications, and activity. Treatment note and any correspondence with referring physicians are completed.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	01/2014				
Presenter(s):	Stephen Levine, PT, DPT, MSHA				
Specialty(s):	American Physical Therapy Association				
CPT Code:	29530				
Sample Size:	984	**Resp N:**	9	**Response:** 0.9 %	
Description of Sample:	Randomly chosen from APTA's database of physical therapists in outpatient practice.				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	10.00	**12.00**	20.00	30.00
Survey RVW:	0.35	0.39	**0.40**	0.50	10.00
Pre-Service Evaluation Time:			**15.00**		
Pre-Service Positioning Time:			**2.00**		
Pre-Service Scrub, Dress, Wait Time:			**1.00**		
Intra-Service Time:	0.00	7.00	**10.00**	15.00	20.00

Immediate Post Service-Time:	**3.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

5 - NF Procedure without sedation/anesthesia care

CPT Code:	29530	**Recommended Physician Work RVU: 0.39**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**7.00**	**7.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**1.00**	**-1.00**
Intra-Service Time:		**9.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

7A Local/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**2.00**	**16.00**	**-14.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
29540	000	0.39	**RUC Time**

CPT Descriptor Strapping; ankle and or foot

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97110	XXX	0.45	**RUC Time**	44,238,381

CPT Descriptor 1 Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
97124	XXX	0.35	**RUC Time**	806,701

CPT Descriptor 2 Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO KEY REFERENCE SERVICE(S):
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Key Reference Code: 14 **% of respondents:** 63.6 **%**

TIME ESTIMATES (Median)	**CPT Code: 29530**	**Key Reference CPT Code:** 29540	**Source of Time** **RUC Time**

Median Pre-Service Time	7.00	7.00
Median Intra-Service Time	9.00	9.00
Median Immediate Post-service Time	2.00	2.00
Median Critical Care Time	0.0	0.00
Median Other Hospital Visit Time	0.0	0.00
Median Discharge Day Management Time	0.0	0.00
Median Office Visit Time	0.0	0.00
Prolonged Services Time	0.0	0.00
Median Subsequent Observation Care Time	0.0	0.00
Median Total Time	**18.00**	**18.00**
Other time if appropriate		

INTENSITY/COMPLEXITY MEASURES (Mean)	**(of those that selected Key Reference code)**	
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	3.63	3.25
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	3.00	2.88
Urgency of medical decision making	2.00	2.00
Technical Skill/Physical Effort (Mean)		
Technical skill required	3.75	3.50
Physical effort required	2.63	2.50
Psychological Stress (Mean)		
The risk of significant complications, morbidity and/or mortality	2.13	1.88
Outcome depends on the skill and judgment of physician	3.75	3.75
Estimated risk of malpractice suit with poor outcome	2.00	1.88

INTENSITY/COMPLEXITY MEASURES	**CPT Code**	**Reference Service 1**
Time Segments (Mean)		
Pre-Service intensity/complexity	2.50	2.50
Intra-Service intensity/complexity	3.50	3.25
Post-Service intensity/complexity	2.63	2.63

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The strapping codes being presented were identified in a CMS/RAW edit for increased utilization. Four codes were identified, however there were two additional codes in the family that were Harvard value and thus six codes are being brought forward. There are a total of eight codes in the family and the two remaining codes in the family (strapping, ankle and strapping, toes, 29540 and 29550, respectively) were presented to the RUC in 2010.

While the six codes were surveyed by APTA, it was recognized that code 29280, strapping, hand/finger, was primarily reported by Occupational Therapists (22% OT, 13% PT). APTA made contact with AOTA who provided a random sample of OTs to include in the survey for this one code. APTA was the primary provider of the other five codes.

The survey codes were distributed to a random selection of PTs obtained from APTA's membership data base of PTs in private practice. Three groups of 1,000 PTs were randomly selected and each group received two codes to review in order to address the survey burden and hopefully increase response rates. As noted, AOTA added approximately 200 randomly selected OTs for the survey of 29280 (strapping, hand/finger).

APTA convened an expert panel to review the results of the surveys. The most striking feature was the four of the surveyed codes returned similar results for the median work value (codes 29200, 29240, 29260, 29530). These values were in line with the reference code chosen, 29540 (strapping, ankle). A fifth code (29520, strapping, hip), which also used the reference code 29540 (strapping, ankle) gave very slightly different numbers for the work value.

The sixth code 29280, strapping, hand/finger had different results. The primary reference code selected by 9 of the respondents was 29126 (Splints, dynamic) and this may have impacted the results. Please note however, that 8 respondents used the 29540 (strapping, ankle) as the primary reference code, ie, the reference code selected in each of the other five codes surveyed. An analysis of the respondents to this survey did not show any significant differences in survey data based on whether an OT or a PT completed the survey.

APTA shared the results of this survey with the AOTA for their thoughts and the development of a joint recommendation to present to the HCPAC. Based on the sample sized obtained and the strong correlation of the codes to the reference code 29540 (strapping, ankle), the recommendation is for the work values for all six of the codes to be the same as the reference code and the SOR were thus completed.

In contrast to the work values, the pre, intra and post service minutes had a wide range of values. A clinical review by the expert panel was unable to support this range of minutes and the expert panel believes that the appropriate minutes should be those used in the primary reference code 29540 (strapping, ankle). These minutes are 7 pre, 9, intra and 2 post.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and

accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) Previously reported as the same code

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty APTA How often? Sometimes

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 100000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 50,622 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Musculoskeletal

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number 29530

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix.

SS Rec Summary

ISSUE: Strapping Codes 29200, 29240, 29260, 29280, 29520, 29530

TAB: B1

Source	CPT	DESC	Resp	IWPUT	RVW MIN	RVW 25th	RVW MED	RVW 75th	RVW MAX	Total Time	PRE-TIME EVAL	PRE-TIME POSIT	PRE-TIME SDW	INTRA-TIME MIN	INTRA-TIME 25th	INTRA-TIME MED	INTRA-TIME 75th	INTRA-TIME MAX	IMMD POST	FAC-inpt/same day 91	92	33	32	31	38	39	FAC-obs 26	25	24	17	Office 15	14	13	12	11	Prolonged 54	55	56	57
REF	29540	Strapping; ankle/foot		0.021			0.39			18	7					9			2																			
HVD	29200	Strapping; thorax		0.017			0.65			34	7					19			8																			
SVY	29200	Strapping; thorax	22	-0.024	0.25	0.39	0.40	0.64	5.00	51.5	22.5	5	4	0	10	15	19	45	5																		
REC	29200	Strapping; thorax		0.021			0.39			18	7	0	0			9			2																		
HVD	29240	Strapping; shoulder		0.016			0.71			39	7					24			8																			
SVY	29240	Strapping; shoulder	23	-0.024	0.25	0.39	0.40	0.58	10.00	52	20	5	5	0	13	15	20	60	7																		
REC	29240	Strapping; shoulder		0.021			0.39			18	7	0	0			9			2																		
HVD	29260	Strapping; elbow/wrist		0.014			0.55			31	6					18			7																			
SVY	29260	Strapping; elbow/wrist	14	0.005	0.00	0.39	0.40	0.64	4.00	29.5	6.5	2.5	0.5	0	10	15	19	45	5																		
REC	29260	Strapping; elbow/wrist		0.021			0.39			18	7	0	0			9			2																		
HVD	29280	Strapping; hand/finger		0.007			0.51			39	7					24			8																			
SVY	29280	Strapping; hand/finger	23	-0.024	0.25	0.39	0.40	0.58	10.00	52	20	5	5	0	13	15	20	60	7																		
REC	29280	Strapping; hand/finger		0.021			0.39			18	7	0	0			9			2																		
HVD	29520	Strapping; hip		0.007			0.54			41	8					24			9																			
SVY	29520	Strapping; hip	9	-0.024	0.35	0.40	0.49	0.51	10.00	39	20	5	1	0	7	8	12	30	5																		
REC	29520	Strapping; hip		0.021			0.39			18	7	0	0			9			2																		
HVD	29530	Strapping; knee		0.009			0.57			38	8					21			9																			
SVY	29530	Strapping; knee	9	-0.006	0.35	0.39	0.40	0.50	10.00	31	15	2	1	0	7	10	15	20	3																		
REC	29530	Strapping; knee		0.021			0.39			18	7	0	0			9			2																		

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:
29200: Strapping; thorax

Global Period OOO Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

Advisors from APTA reviewed the PE details for code 29200 and reference code 29540.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: Patients that undergo 29200 and 29540 are very similar in terms of age, and diagnosis. The main difference is the location where strapping occurs.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time: N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence: N/A

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Complete pre-service diagnostic & referral forms.

Intra-Service Clinical Labor Activities:

Preparing the patient and room: Greet patient, provide gowning, ensure appropriate medical records are available. Provide pre-service education/obtain consent. Prepare and position the patient. Prepare the room and equipment (gloves and strapping/tape).

Assist provider with performing the procedure, which includes placing the patient in an appropriate position to allow body parts to be strapped and held in a comfortable position before applying the strapping materials.

Immediately after the procedure: clean the room and equipment by physician staff. After completion of the procedure, discard gloves and any contaminated materials.

Check strapping, provide home care instructions and coordinate follow-up.

<u>Post-Service</u> Clinical Labor Activities:

Conduct phone call(s) to assess response, answer any questions and provide follow-up as necessary.

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:
29240: Strapping; shoulder (eg, Velpeau)

Global Period OOO Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

Advisors from APTA reviewed the PE details for code 29200 and reference code 29540.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: Patients that undergo 29240 and 29540 are very similar in terms of age, and diagnosis. The main difference is the location where strapping occurs.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time: N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence: N/A

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Complete pre-service diagnostic & referral forms.

Intra-Service Clinical Labor Activities:

Preparing the patient and room: Greet patient, provide gowning, ensure appropriate medical records are available. Provide pre-service education/obtain consent. Prepare and position the patient. Prepare the room and equipment (gloves and strapping/tape).

Assist provider with performing the procedure, which includes placing the patient in an appropriate position to allow body parts to be strapped and held in a comfortable position before applying the strapping materials.

Immediately after the procedure: clean the room and equipment by physician staff. After completion of the procedure, discard gloves and any contaminated materials.

Check strapping, provide home care instructions and coordinate follow-up.

<u>Post-Service</u> Clinical Labor Activities:

Conduct phone call(s) to assess response, answer any questions and provide follow-up as necessary.

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:
29260: Strapping: elbow, or wrist

Global Period OOO Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

Advisors from APTA reviewed the PE details for code 29260 and reference code 29540.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: Patients that undergo 29260 and 29540 are very similar in terms of age, and diagnosis. The main difference is the location where strapping occurs.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time: N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence: N/A

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Complete pre-service diagnostic & referral forms.

Intra-Service Clinical Labor Activities:

Preparing the patient and room: Greet patient, provide gowning, ensure appropriate medical records are available. Provide pre-service education/obtain consent. Prepare and position the patient. Prepare the room and equipment (gloves and strapping/tape).

Assist provider with performing the procedure, which includes placing the patient in an appropriate position to allow body parts to be strapped and held in a comfortable position before applying the strapping materials.

Immediately after the procedure: clean the room and equipment by physician staff. After completion of the procedure, discard gloves and any contaminated materials.

Check strapping, provide home care instructions and coordinate follow-up.

<u>Post-Service</u> Clinical Labor Activities:

Conduct phone call(s) to assess response, answer any questions and provide follow-up as necessary.

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:
29280: Strapping; hand/finger

Global Period OOO Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

Advisors from AOTA and APTA reviewed the PE details for code 29280 and reference code 29540.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: Patients that undergo 29280 and 29540 are very similar in terms of age, and diagnosis. The main difference is the location where strapping occurs.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time: N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence: N/A

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Complete pre-service diagnostic & referral forms.

Intra-Service Clinical Labor Activities:

Preparing the patient and room: Greet patient, provide gowning, ensure appropriate medical records are available. Provide pre-service education/obtain consent. Prepare and position the patient. Prepare the room and equipment (gloves and strapping/tape).

Assist provider with performing the procedure, which includes placing the patient in an appropriate position to allow body parts to be strapped and held in a comfortable position before applying the strapping materials.

Immediately after the procedure: clean the room and equipment by physician staff. After completion of the procedure, discard gloves and any contaminated materials.

Check strapping, provide home care instructions and coordinate follow-up.

<u>Post-Service</u> Clinical Labor Activities:

Conduct phone call(s) to assess response, answer any questions and provide follow-up as necessary.

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:
29520: Strapping; hip

Global Period OOO Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

Advisors from APTA reviewed the PE details for code 29520 and reference code 29540.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: Patients that undergo 29520 and 29540 are very similar in terms of age, and diagnosis. The main difference is the location where strapping occurs.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time: N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence: N/A

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Complete pre-service diagnostic & referral forms.

Intra-Service Clinical Labor Activities:

Preparing the patient and room: Greet patient, provide gowning, ensure appropriate medical records are available. Provide pre-service education/obtain consent. Prepare and position the patient. Prepare the room and equipment (gloves and strapping/tape).

Assist provider with performing the procedure, which includes placing the patient in an appropriate position to allow body parts to be strapped and held in a comfortable position before applying the strapping materials.

Immediately after the procedure: clean the room and equipment by physician staff. After completion of the procedure, discard gloves and any contaminated materials.

Check strapping, provide home care instructions and coordinate follow-up.

<u>Post-Service</u> Clinical Labor Activities:

Conduct phone call(s) to assess response, answer any questions and provide follow-up as necessary.

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:
29520: Strapping; knee

Global Period OOO Meeting Date: January 2014

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

Advisors from APTA reviewed the PE details for code 29530 and reference code 29540.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale: Patients that undergo 29530 and 29540 are very similar in terms of age, and diagnosis. The main difference is the location where strapping occurs.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time: N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence: N/A

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Complete pre-service diagnostic & referral forms.

Intra-Service Clinical Labor Activities:

Preparing the patient and room: Greet patient, provide gowning, ensure appropriate medical records are available. Provide pre-service education/obtain consent. Prepare and position the patient. Prepare the room and equipment (gloves and strapping/tape).

Assist provider with performing the procedure, which includes placing the patient in an appropriate position to allow body parts to be strapped and held in a comfortable position before applying the strapping materials.

Immediately after the procedure: clean the room and equipment by physician staff. After completion of the procedure, discard gloves and any contaminated materials.

Check strapping, provide home care instructions and coordinate follow-up.

<u>Post-Service</u> Clinical Labor Activities:

Conduct phone call(s) to assess response, answer any questions and provide follow-up as necessary.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U
1				REFERENCE CODE																	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code. **Please note: If you are including clinical labor tasks that are not listed on this spreadsheet please list them as subcategories of established clinical labor tasks whenever possible. Please see the *PE Spreadsheet Instructions* document for an example.**			**29540**		**29200**		**29240**		**29260**		**29280**		**29520**		**29530**		**29540**		**29550**	
3	**Meeting Date: Tab: Specialty:**	**CMS Code**	**Staff Type**	Strapping; ankle/foot		Strapping, thorax		Strapping; shoulder		Strapping, elbow/wrist		Strapping; hand/finger		Strapping, hip		Strapping; knee		Strapping; ankle/foot		Strapping; toes	
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**																				
6	**TOTAL CLINICAL LABOR TIME**			**27.0**	**0.0**	**21.0**	**0.0**	**21.0**	**0.0**	**21.0**	**0.0**	**21.0**	**0.0**	**21.0**	**0.0**	**21.0**	**0.0**	**21.0**	**0.0**	**21.0**	**0.0**
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
8	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**24.0**	**0.0**	**18.0**	**0.0**	**18.0**	**0.0**	**18.0**	**0.0**	**18.0**	**0.0**	**18.0**	**0.0**	**18.0**	**0.0**	**18.0**	**0.0**	**18.0**	**0.0**
9	**TOTAL POST-SERV CLINICAL LABOR TIME**			**3.0**	**0.0**	**3.0**	**0.0**	**3.0**	**0.0**	**3.0**	**0.0**	**3.0**	**0.0**	**3.0**	**0.0**	**3.0**	**0.0**	**3.0**	**0.0**	**3.0**	**0.0**
10	**PRE-SERVICE**																				
11	**Start: Following visit when decision for surgery or procedure made**																				
12	Complete pre-service diagnostic & referral forms		PTA	**0**		**0**		**0**		**0**		**0**		**0**		**0**		**0**		**0**	
13	Coordinate pre-surgery services																				
14	Schedule space and equipment in facility																				
15	Provide pre-service education/obtain consent																				
16	Follow-up phone calls & prescriptions																				
17	*Other Clinical Activity - *specify:*																				
18	**End: When patient enters office/facility for surgery/procedure**																				
19	**SERVICE PERIOD**																				
20	**Start: When patient enters office/facility for surgery/procedure:**																				
21	Greet patient, provide gowning, ensure appropriate medical records are available		PT Aide	**3**		**0**		**0**		**0**		**0**		**0**		**0**		**0**		**0**	
22	Obtain vital signs																				
23	Provide pre-service education/obtain consent		PT Aide	**3**		**3**		**3**		**3**		**3**		**3**		**3**		**3**		**3**	
24	Prepare room, equipment, supplies		PT Aide	**5**		**2**		**2**		**2**		**2**		**2**		**2**		**2**		**2**	
25	Setup scope (non facility setting only)																				
26	Prepare and position patient/ monitor patient/ set up IV		PT Aide	**2**		**2**		**2**		**2**		**2**		**2**		**2**		**2**		**2**	
27	Sedate/apply anesthesia																				
28	*Other Clinical Activity - specify:																				
29	**Intra-service**																				
30	Assist physician in performing procedure		PT Aide	**8**		**8**		**8**		**8**		**8**		**8**		**8**		**8**		**8**	
31	Assist physician/moderate sedation (% of physician time)																				
32	**Post-Service**																				
33	Monitor pt. following moderate sedation																				
34	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)																				
35	Clean room/equipment by physician staff		PT Aide	**3**		**3**		**3**		**3**		**3**		**3**		**3**		**3**		**3**	
36	Clean Scope																				
37	Clean Surgical Instrument Package																				
38	Complete diagnostic forms, lab & X-ray requisitions																				
39	Review/read X-ray, lab, and pathology reports																				
40	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions		PTA																		
41	*Other Clinical Activity - *specify:*																				
42	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)			**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**	
43	Dischrg mgmt (1.0 x 99238) (enter 12 min)			**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**	
44	Dischrg mgmt (1.0 x 99239) (enter 15 min)			**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**	
45	**End: Patient leaves office**																				
46	**POST-SERVICE Period**																				
47	**Start: Patient leaves office/facility**																				
48	Conduct phone calls/call in prescriptions		PTA	**3**		**3**		**3**		**3**		**3**		**3**		**3**		**3**		**3**	
49	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**
50	99211 16 minutes		16																		
51	99212 27 minutes		27																		
52	99213 36 minutes		36																		
53	99214 53 minutes		53																		
54	99215 63 minutes		63																		
55	**Total Office Visit Time**			**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
56	*Other Clinical Activity - *specify:*																				
57	**End: with last office visit before end of global period**																				
58	**MEDICAL SUPPLIES****	**CODE**	**UNIT**																		
59	gloves (non-sterile)	SB022	pair	**2**		**2**		**2**		**2**		**2**		**2**		**2**		**2**		**2**	
60	tape, surgical paper 1in (Micropore)	SG079	inch	**6**		**6**		**6**		**6**		**6**		**6**		**6**		**6**		**6**	
61	foam underwrap		inch	**60**		**130**		**80**		**45**		**30**		**175**		**75**		**48**		**22**	
62	rigid strapping tape		inch	**60**		**130**		**80**		**45**		**30**		**175**		**75**		**48**		**22**	
63	skin prep barrier wipes		each	**1**		**2**		**2**		**1**		**1**		**2**		**2**		**1**		**1**	
64	**EQUIPMENT**	**CODE**																			
65																					

AMA/Specialty Society RVS Update Committee **Tab 34**
Practice Expense Subcommittee
January 29-30, 2014

Members Present: Scott Manaker, MD, PhD, FCCP (Chair), Albert Bothe, MD (CPT), James Blankenship, MD, Joel Brill, MD, Neal Cohen, MD, Thomas Cooper, MD, David Han, MD, Timothy Laing, MD, Alan Lazaroff, MD, Geraldine B. McGinty, MD, Eileen M. Moynihan, MD, Tye Ouzounian, MD, John Seibel, MD, W Bryan Sims, DNP, APRN-BC, FNP, Robert Stomel, DO, Thomas J. Weida, MD

I. Moderate Sedation Monitoring Time Workgroup

The Moderate Sedation Monitoring Time Workgroup met on December 4, 2013 via conference call to review information from the specialty societies regarding the clinical necessity of both the mandatory clinical staff and amount of time necessary for post-procedure monitoring. Upon reviewing clinical practice guidelines and published literature provided by the specialty societies the Workgroup determined that an RN for patient monitoring is typical and medically necessary for the 56 codes still under review by the Workgroup. The supporting documentation provided, as well as a letter of support from the American Nurses Association (ANA), are included as attachments to this report and will be included in the Workgroups recommendation to CMS.

Following the conference call the Workgroup voted by email on the following two issues:

- For the procedures in question, do you support use of an RN as the clinical staff type for post-procedure patient monitoring following 1 hour (15 minutes) of monitoring for moderate sedation, Yes or No?
- Do you support the final time recommendations for the codes reviewed (see attached spreadsheet), Yes or No?

The Workgroup members voted yes unanimously on both issues.

The Practice Expense (PE) Subcommittee offers the following recommendations to the RUC:

- **The 56 codes included in the review should be standardized to the clinical staff times listed in the attached spreadsheet.**
- **The 56 codes included in the review should maintain an RN as the clinical staff type for post-procedure monitoring not related to moderate sedation.**

II. Moderate Sedation Standard Package

Currently the moderate sedation standard package does not include a stretcher (sometimes refer to as a gurney). Many specialty societies that perform procedures with moderate sedation have indicated that a stretcher is needed and include it as a separate equipment direct PE input in their recommendations to the PE Subcommittee. The PE Subcommittee agrees that it is a necessary direct PE input and has determined that it should be added to the moderate sedation standard package. **The PE Subcommittee is recommending that the RUC add a stretcher (EF018) to the standard package, as well as three scenarios for its use.**

Scenarios for stretcher use:

- **Consistent use throughout procedure – patient is wheeled in on the stretcher and remains on the stretcher for the entirety of the procedure. Patient recovers on the stretcher.**
- **Short procedure, cannot be used by another patient – patient is wheeled in on the stretcher, but is moved for the procedure. The stretcher remains with the patient and the patient recovers on the stretcher.**
- **Long procedure, can be used by another patient – patient is wheeled in on the stretcher, but is moved for the procedure. The linens are changed and the stretcher can be used for other patients. Patient recovers on a different stretcher.**

Although the other equipment items in the standard package, *table, instrument, mobile* (EF027) , *ECG, 3-channel (with SpO2, NIBP, temp, resp)* (EQ011) and *IV infusion pump* (EQ032), would typically have the same number of minutes, equipment time for the stretcher should be based on the typical scenario for the service.

Additionally the RUC will be forming a joint CPT/RUC Workgroup to examine the implications of independent anesthesiologists (and CRNAs) performing anesthesia services for codes that previously were valued including moderate sedation. The Chair has been tasked with appointing representatives of the PE Subcommittee to serve on this Workgroup.

III. Outpatient Prospective Payment System and Ambulatory Surgical Center Cap

CMS requested broad feedback and recommendations regarding changes to the PE methodology. Pathology reported that 20% of their services are impacted by the OPPS/ASC Payment Cap. They explained that hospital cost analysis is not performed code by code as it is for the physician fee schedule and that hospital payments do not cover Pathology costs for these services. Interventional Radiology concurred with Pathology's statement and added that APC payments are not a reliable method for determining practice expense for all physician services. They continued that APC payments are an average that includes over- and underpayment in the hospital setting. Physicians' offices do not have the luxury of being able to absorb costs that exceed payment. CMS added that the Hospital Outpatient Panel (HOP), a federal advisory commission, is receptive to presentations from the specialty societies. Presentation guidelines can be found online and presentations can still be submitted in time for the March 2014 HOP meeting, regarding appropriate placement within APC groups. The Chair notes that two RUC members and a specialty society RUC advisor currently service on the HOP.

Following publication of the 2014 Final Rule, the RUC solicited feedback from the specialties societies regarding CPT codes potentially impacted by the OPPS/ASC Payment Cap. Specialty societies indicated an interested in re-reviewing or validating a recent RUC review, for 63 of the 211 codes identified through the cap. **The PE Subcommittee will review the codes identified by specialty societies, grouped by families, at the April 2014 RUC meeting and provide CMS with the recommendations as a sample subset of the codes impacted by the cap. Other services from the list of 211 that have been recently reviewed will also be identified to CMS.**

IV. Other Business

Direct PE Inputs Refinement

A PE Subcommittee member expressed interest in developing a formal appeals process for PE refinements. Currently the RUC solicits comments from the specialty societies for each refinement, collates the information, and submits the information to CMS. CMS assured the PE

Subcommittee that these comments are taken seriously and are considered in their rulemaking. **The PE Subcommittee will discuss an appeals process for PE refinements at the April 2014 RUC meeting.**

PPI Survey
A PE Subcommittee member suggested that CMS explore a new PPI survey

V. Practice Expense Recommendations for CPT 2015

Tab	Title	PE Input Changes (Yes or No)
4	Arthrocentesis	Yes Minor Modifications
5	Internal Fixation of Rib Fracture	Yes Minor Modifications
6	FEVAR Endograft Planning	No PE recommendation Carrier Priced
7	Endoscopic Hypopharyngeal Diverticulotomy	No 090 Global Standard
8	Colonoscopy through stoma	Yes Minor Modifications
9	Flexible Sigmoidoscopy	No
10	Colonoscopy	Yes Minor Modifications
11	Myelography	No PE recommendation Withdrawn from Review
12	Aqueous Shunt	No
13	Breast Ultrasound	Yes Minor Modifications
14	Radiation Treatment Delivery	Yes Minor Modifications
15	Bioimpedance Spectroscopy	Yes Minor Modifications
16	Brief Behavioral Assessment	No PE recommendation Refer to CPT

Tab	Title	PE Input Changes (Yes or No)
17	Negative Pressure Wound Therapy	Yes Minor Modifications
18	Selective Head and Total Body Hypothermia	No PE recommendation
19	End of Life Care-Advance Directive Plan	Yes Minor Modifications
20	Hormone Pellet Implantation	Yes Modifications/Handout
21	Injection for Knee Arthrography	No PE recommendation Not Surveyed
22	Endobronchial Ultrasound	No
23	Bronchoscopy-Computer Assisted	No
24	Laparoscopic Hysterectomy	No PE recommendation Postponed
25	Percutaneous Implantation of Neuroelectrodes	Yes Modifications/Handout
26	X-Ray Exams	No PE recommendation
27	CT Angiography-Chest	Yes Minor Modifications
28	Swallowing Function	No
29	Microdissection	Yes Modifications/Handout
30	Doppler Echocardiography	Yes Minor Modifications
31	Continuous Glucose Monitoring	No PE recommendation Postponed
32	Electronic Analysis of Implanted Neurostimulator Pulse Generator System	Yes Minor Modifications

Tab	Title	PE Input Changes (Yes or No)
33	Hyperbaric Oxygen Therapy	Yes Modifications/Handout
35	Strapping Procedures (HCPAC)	Yes Modifications/Handout

AMA/Specialty Society RVS Update Committee
Practice Expense Subcommittee
Moderate Sedation Monitoring Time Workgroup
Wednesday December 4, 2013 Conference Call
7pm-8pm CST

Conference Call Report

Members participating on call: *Margaret Neal, MD (Chair), Timothy Laing, MD, Jeremy S. Musher, MD, Guy Orangio, MD, James C. Waldorf, MD, Adam Weinstein, MD, Jennifer L. Wiler, MD*

The Moderate Sedation Monitoring Time Workgroup met on December 4, 2013 via conference call. On the previous conference call the Workgroup determined that they needed more information from the specialty societies regarding the clinical necessity of both the mandatory clinical staff and amount of time necessary for post-procedure monitoring. The Workgroup asked for clarification on the following:

- Why the clinical staff type should be a Registered Nurse (RN) rather than a blend for post-procedure monitoring following recovery from moderate sedation.
- The amount of time needed for post-procedure monitoring following recovery from moderate sedation?

For the December 4th call the specialty societies provided supporting documents for the Workgroup's review regarding the 56 codes still under review by the Workgroup. The specialty societies provided clinical practice guidelines and published literature regarding the procedures in question. Additionally they provided information indicating that California and Florida both require an RN by law for all patient' monitoring. The specialties made the case that this constitutes the typical scenario since these two states alone represent 40% of all Medicare beneficiaries.

Clinical Staff Type

Initially the Workgroup expressed some reservation that the materials provided constituted a "standard national protocol" (e.g. published literature, Joint Commission requirements and/or society clinical practice guidelines) regarding an RN as the mandatory clinical staff type for post-procedure monitoring not related to moderate sedation, because the materials did not specify the level of training required. The specialty society advisors, including strong support from the American Nurses Association (ANA), clarified that although it has been difficult to come forward with a "standard national protocol" in writing, after querying their membership, it is clear an RN is the only staff type permitted to monitor patients after the type of high risk procedures that the Workgroup is reviewing. A representative of the ANA stated that the clinical staff must be an RN because patient assessment is an RN competency. The RN is needed to assess the patient and determine when discharge is appropriate. This is a nurse function and cannot be delegated to a licensed practical nurse (LPN). Many of the Workgroup members agreed that it is policy in the facility setting to have a RN do all patient' monitoring and that nonfacility practices would follow the same standards as a facility when performing the same procedures.

Clinical Staff Time

The Workgroup went through each of the 56 codes to determine if the clinical staff was appropriate. The monitoring time for two procedures was modified, and is noted in red in the attached spreadsheet.

Workgroup Vote

The Chair determined that the Workgroup members will vote by email on the following two issues:

- For the procedures in question, do you support use of an RN as the clinical staff type for post-procedure patient monitoring following 1 hour (15 minutes) of monitoring for moderate sedation, Yes or No?
- Do you support the final time recommendations for the codes reviewed (see attached spreadsheet), Yes or No?

The Workgroup members were given a week to vote. One Workgroup member, whom was not able to be on the call, abstained from voting. The Workgroup members voted yes unanimously on both issues.

Workgroup Recommendations:

The Workgroup offers the following recommendations for discussion and acceptance by the Practice Expense Subcommittee at the January 2014 RUC meeting:

- **The 56 codes included in the review should be standardized to the clinical staff times listed in the attached spreadsheet.**
- **The 56 codes included in the review should maintain an RN as the clinical staff type for post-procedure monitoring not related to moderate sedation.**

CPT Code	Short Descriptor	Global	**Current Monitoring Time (Min)**	2011 Top Specialty/ *Survey Specialty*	2011 Total Frequency	**Specialty Recommended Post-Procedure Mod Sed Monitoring Time (Min)**	**Specialty Recommended Post- Procedure Monitoring Time (Min)**	**Approved by Workgroup**	Specialty Society Rationale
32405	PERCUT BX LUNG/MEDIASTINUM	000	**60**	DIAGNOSTIC RADIOLOGY	61,487	15	45	Yes	Percutaneous lung biopsy procedures require a MINIMUM of 4 hours postprocedure recovery to assess for pneumothorax, pulmonary hemorrhage, etc.
32553	INS MARK THOR FOR RT PERQ	000	**30**	DIAGNOSTIC RADIOLOGY	1,898	15	45	Yes	Placement of intrathoracic fiducial markers is an extension of lung biopsy techniques and thus requires a MINIMUM of 4 hours postprocedure recovery to assess for pneumothorax, pulmonary hemorrhage, etc.
35471	REPAIR ARTERIAL BLOCKAGE	000	**21**	CARDIOLOGY	8,843	15	45	Yes	
35475	REPAIR ARTERIAL BLOCKAGE	000	**60**	NEPHROLOGY	41,260	15	15	Yes	
35476	REPAIR VENOUS BLOCKAGE	000	**60**	DIAGNOSTIC RADIOLOGY	274,832	15	15	Yes	
36147	ACCESS AV DIAL GRFT FOR EVAL	XXX	**18**	DIAGNOSTIC RADIOLOGY	297,571	15	15	Yes	Dialysis AV graft diagnostic procedures require a MINIMUM of 2 hours postprocedure recovery to assess for bleeding from access sites in a high pressure circuit following use of large sheaths for access.
36200	PLACE CATHETER IN AORTA	000	**60**	VASCULAR SURGERY	72,214	15	45	Yes	Arterial Standard (see document)
36221	PLACE CATH THORACIC AORTA	000	**60**	*VASCULAR SURGERY*		15	45	Yes	Arterial Standard (see document)
36222	PLACE CATH CAROTID/INOM ART	000	**60**	*DIAGNOSTIC RADIOLOGY*		15	45	Yes	Arterial Standard (see document)
36223	PLACE CATH CAROTID/INOM ART	000	**60**	*DIAGNOSTIC RADIOLOGY*		15	45	Yes	Arterial Standard (see document)
36224	PLACE CATH CAROTD ART	000	**60**	*DIAGNOSTIC RADIOLOGY*		15	45	Yes	Arterial Standard (see document)
36225	PLACE CATH SUBCLAVIAN ART	000	**60**	*CARDIOLOGY*		15	45	Yes	Arterial Standard (see document)
36226	PLACE CATH VERTEBRAL ART	000	**60**	*DIAGNOSTIC RADIOLOGY*		15	45	Yes	Arterial Standard (see document)
36245	INS CATH ABD/L-EXT ART 1ST	XXX	**60**	CARDIOLOGY	113,568	15	45	Yes	Arterial Standard (see document)
36246	INS CATH ABD/L-EXT ART 2ND	000	**60**	CARDIOLOGY	44,405	15	45	Yes	Arterial Standard (see document)
36247	INS CATH ABD/L-EXT ART 3RD	000	**60**	DIAGNOSTIC RADIOLOGY	57,020	15	45	Yes	Arterial Standard (see document)
36251	INS CATH REN ART 1ST UNILAT	000	**60**	*CARDIOLOGY*		15	45	Yes	Arterial Standard (see document)
36252	INS CATH REN ART 1ST BILAT	000	**60**	*CARDIOLOGY*		15	45	Yes	Arterial Standard (see document)
36253	INS CATH REN ART 2ND+ UNILAT	000	**60**	*CARDIOLOGY*		15	45	Yes	Arterial Standard (see document)
36254	INS CATH REN ART 2ND+ BILAT	000	**60**	*CARDIOLOGY*		15	45	Yes	Arterial Standard (see document)
36481	INSERTION OF CATHETER VEIN	000	**60**	DIAGNOSTIC RADIOLOGY	822	15	45	Yes	Percutaneous portal vein catheterization procedures require a MINIMUM of 4 hours postprocedure recovery to assess for late complcations associated with traversing the liver, including bleeding, peritonitis secondary to bile leak, etc.
37183	REMOVE HEPATIC SHUNT (TIPS)	000	**60**	DIAGNOSTIC RADIOLOGY	704	15	45	Yes	TIPS revision procedures require a MINIMUM of 4 hours postprocedure recovery to assess for late complcations associated with use of large diameter 8-12 Fr sheaths.
37191	INS ENDOVAS VENA CAVA FILTR	000	**60**	*DIAGNOSTIC RADIOLOGY*		15	15	Yes	
37192	REDO ENDOVAS VENA CAVA FILTR	000	**60**	*VASCULAR SURGERY*		15	45	Yes	Vena Cava filter repositioning procedures require a MINIMUM of 4 hours postprocedure recovery due to potential complications associated with use of larger 10 Fr and 12 Fr sheaths and thrombosis/occlusion of the IVC.
37193	REM ENDOVAS VENA CAVA FILTER	000	**60**	*DIAGNOSTIC RADIOLOGY*		15	45	Yes	Vena Cava filter retrieval procedures require a MINIMUM of 4 hours postprocedure recovery due to potential complications associated with use of larger 10 Fr and 12 Fr sheaths and potential bleeding/thrombosis of vena cava filter attachment site.
37197	REMOVE INTRVAS FOREIGN BODY	000	**60**	*VASCULAR SURGERY*		15	45	Yes	Intravascular foreign body retrieval procedures may be either arterial or venous but both require larger bore tools to retrieve the foreign body from the vascular system.
37210	EMBOLIZATION UTERINE FIBROID	000	**60**	DIAGNOSTIC RADIOLOGY	358	15	45	Yes	Arterial Standard (see document)
37220	ILIAC REVASC	000	**60**	VASCULAR SURGERY	11,133	15	45	Yes	Arterial Standard (see document)
37221	ILIAC REVASC W/STENT	000	**60**	VASCULAR SURGERY	37,131	15	45	Yes	Arterial Standard (see document)
37224	FEM/POPL REVAS W/TLA	000	**60**	VASCULAR SURGERY	30,764	15	45	Yes	Arterial Standard (see document)
37225	FEM/POPL REVAS W/ATHER	000	**60**	CARDIOLOGY	21,844	15	45	Yes	Arterial Standard (see document)
37226	FEM/POPL REVASC W/STENT	000	**60**	CARDIOLOGY	33,175	15	45	Yes	Arterial Standard (see document)
37227	FEM/POPL REVASC STNT & ATHER	000	**60**	CARDIOLOGY	9,639	15	45	Yes	Arterial Standard (see document)
37228	TIB/PER REVASC W/TLA	000	**60**	VASCULAR SURGERY	23,037	15	45	Yes	Arterial Standard (see document)
37229	TIB/PER REVASC W/ATHER	000	**60**	CARDIOLOGY	12,263	15	45	Yes	Arterial Standard (see document)
37230	TIB/PER REVASC W/STENT	000	**60**	CARDIOLOGY	3,459	15	45	Yes	Arterial Standard (see document)
37231	TIB/PER REVASC STENT & ATHER	000	**60**	CARDIOLOGY	1,192	15	45	Yes	Arterial Standard (see document)
47000	NEEDLE BIOPSY OF LIVER	000	**60**	DIAGNOSTIC RADIOLOGY	55,169	15	45	Yes	Percutaneous liver biopsy procedures require a MINIMUM of 4 hours postprocedure recovery to assess for bleeding, peritonitis, etc. as complications of traversing the liver.
47525	CHANGE BILE DUCT CATHETER	000	**6**	DIAGNOSTIC RADIOLOGY	11,178	15	~~15~~ 0		Biliary drainage catheter exchange procedures require a MINIMUM of 2 hours postprocedure recovery to assess for bleeding, peritonitis, etc.

CPT Code	Short Descriptor	Global	**Current Monitoring Time (Min)**	2011 Top Specialty/ *Survey Specialty*	2011 Total Frequency	**Specialty Recommended Post-Procedure Mod Sed Monitoring Time (Min)**	**Specialty Recommended Post- Procedure Monitoring Time (Min)**	**Approved by Workgroup**	Specialty Society Rationale
49411	INS MARK ABD/PEL FOR RT PERQ	000	**30**	DIAGNOSTIC RADIOLOGY	1,176	15	45	Yes	Placement intraabdominal fiducial markers is an extension of solid organ (e.g. liver) biopsy techniqes and similarly requires a MINIMUM of 4 hours postprocedure recovery to assess for bleeding, peritonitis, bowel perforation, solid organ injury, etc.
49418	INSERT TUN IP CATH PERC	000	**60**	DIAGNOSTIC RADIOLOGY	2,753	15	45	Yes	Placement of tunneled intraperitoneal catheter procedures require a MINIMUM of 4 hours postprocedure recovery to assess for bleeding, peritonitis, bowel perforation, etc.
50593	PERC CRYO ABLATE RENAL TUM	010	**30**	DIAGNOSTIC RADIOLOGY	1,614	15	45	Yes	Percutaneous renal cryoablation procedures uses techniques analagous to solid organ biopsy and thus requires a MINIMUM of 4 hours postprocedure recovery to assess for retroperitoneal bleeding, urine leak, hematuria, etc.
77371	SRS MULTISOURCE	XXX	**30**	NEUROSURGERY	30	15	15	Yes	Necessary b/c the patient has had a (1) headframe removed (nausea) and (2) an entire course of radiation in one sitting and they need to be monitored for complications.
93451	RIGHT HEART CATH	000	**30**	CARDIOLOGY	27,162	15	15	Yes	Venous Standard
93452	LEFT HRT CATH W/VENTRCLGRPHY	000	**60**	CARDIOLOGY	20,500	15	45	Yes	Arterial Standard (see document)
93453	R&L HRT CATH W/VENTRICLGRPHY	000	**60**	CARDIOLOGY	6,636	15	45	Yes	Arterial Standard (see document)
93454	CORONARY ARTERY ANGIO S&I	000	**60**	CARDIOLOGY	81,743	15	45	Yes	Arterial Standard (see document)
93455	CORONARY ART/GRFT ANGIO S&I	000	**60**	CARDIOLOGY	23,485	15	45	Yes	Arterial Standard (see document)
93456	R HRT CORONARY ARTERY ANGIO	000	**60**	CARDIOLOGY	9,556	15	45	Yes	Arterial Standard (see document)
93457	R HRT ART/GRFT ANGIO	000	**60**	CARDIOLOGY	2,519	15	45	Yes	Arterial Standard (see document)
93458	L HRT ARTERY/VENTRICLE ANGIO	000	**60**	CARDIOLOGY	579,029	15	45	Yes	Arterial Standard (see document)
93459	L HRT ART/GRFT ANGIO	000	**60**	CARDIOLOGY	139,083	15	45	Yes	Arterial Standard (see document)
93460	R&L HRT ART/VENTRICLE ANGIO	000	**60**	CARDIOLOGY	96,250	15	45	Yes	Arterial Standard (see document)
93461	R&L HRT ART/VENTRICLE ANGIO	000	**60**	CARDIOLOGY	20,914	15	45	Yes	Arterial Standard (see document)
93505	BIOPSY OF HEART LINING	000	**30**	CARDIOLOGY	14,343	15	15	Yes	Venous Standard
50200	RENAL BIOPSY PERQ	000	**15**	DIAGNOSTIC RADIOLOGY	30,748	15	45		This code was added by the Workgroup to maintain consistency with the recommendations

CPT Code	Short Descriptor	Global	**Current Monitoring Time (Min)**	2011 Top Specialty/ *Survey Specialty*	2011 Total Frequency	**Specialty Recommended Post-Procedure Mod Sed Monitoring Time (Min)**	**Specialty Recommended Post-Procedure Monitoring Time (Min)**	**Specialty Society Rationale**
31625	BRONCHOSCOPY W/BIOPSY(S)	000	**20**	PULMONARY DISEASE	26,903	15	0	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
31626	BRONCHOSCOPY W/MARKERS	000	**25**	PULMONARY DISEASE	1,127	15	0	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
31628	BRONCHOSCOPY/LUNG BX EACH	000	**25**	PULMONARY DISEASE	38,792	15	0	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
31629	BRONCHOSCOPY/NEEDLE BX EACH	000	**25**	PULMONARY DISEASE	19,852	15	0	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
31634	BRONCH W/BALLOON OCCLUSION	000	**25**	PULMONARY DISEASE	120	15	0	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
31645	BRONCHOSCOPY CLEAR AIRWAYS	000	**10**	PULMONARY DISEASE	33,133	15	0	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
31646	BRONCHOSCOPY RECLEAR AIRWAY	000	**10**	PULMONARY DISEASE	4,369	15	0	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time

	A	B	C	D	E	F	G	H	I	J
1	CPT Code	Short Descriptor	Global	**Current Monitoring Time (Min)**	2011 Top Specialty/ *Survey Specialty*	2011 Total Frequency	**Specialty Recommended Post-Procedure Mod Sed Monitoring Time (Min)**	**Specialty Recommended Post-Procedure Monitoring Time (Min)**	**CMS Requested Action to Alter Service Time (Min)**	**Specialty Society Rationale**
2	31625	BRONCHOSCOPY W/BIOPSY(S)	000	**20**	PULMONARY DISEASE	26,903	15	0	-5	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
3	31626	BRONCHOSCOPY W/MARKERS	000	**25**	PULMONARY DISEASE	1,127	15	0	-10	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
4	31628	BRONCHOSCOPY/LUNG BX EACH	000	**25**	PULMONARY DISEASE	38,792	15	0	-10	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
5	31629	BRONCHOSCOPY/NEEDLE BX EACH	000	**25**	PULMONARY DISEASE	19,852	15	0	-10	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
6	31634	BRONCH W/BALLOON OCCLUSION	000	**25**	PULMONARY DISEASE	120	15	0	-10	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
7	31645	BRONCHOSCOPY CLEAR AIRWAYS	000	**10**	PULMONARY DISEASE	33,133	15	0	+5	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time
8	31646	BRONCHOSCOPY RECLEAR AIRWAY	000	**10**	PULMONARY DISEASE	4,369	15	0	+5	Time obtained originally from Crosswalk from older codes, should be only Moderate Sedation Time

Practice Expense Subcommittee
Staff Note – January 2014

Moderate Sedation Standard Package

Currently the moderate sedation standard package does not include a stretcher. Many specialty societies that perform procedures with moderate sedation have indicated that a stretcher is needed and include it as a separate equipment direct PE input in their recommendations to the PE Subcommittee. The PE Subcommittee agrees that it is a necessary direct PE input and has determined that it should be added to the moderate sedation standard package. The PE Subcommittee is recommending that the RUC add a stretcher (EF018) to the standard package. **The revised moderate sedation standard will be (change in red):**

Clinical Labor:

RN - 2 minutes to initiate sedation
RN - 100% of the physician intra-service work time
RN - 15 minutes of RN time for every hour for post-service patient monitoring

Moderate Sedation Clinical Labor Standards- Updated October 2013

The standard time for post-procedure monitoring attributed to moderate sedation monitoring should be 1 hour (1:4 nurse/patient ratio – resulting in 15 minutes of clinical staff time (RN staff type). The maximum time for post-procedure monitoring, not related to moderate sedation, should be 1 hour (1:4 nurse/patient ratio – resulting in 15 minutes of clinical staff time (RN/LPN/MTA blend). This would make the maximum standard for post-procedure monitoring time 30 minutes. As with other standards specialties can provide compelling evidence that more time is justified.

Medical Supplies:

Standard Moderate Sedation Package: The contents of this package are:

	Code	Unit	Qty	Unit price
pack, conscious sedation	**SA044**	**pack**		**17.311**
angiocatheter 14g-24g		item	1	1.505
bandage, strip 0.75in x 3in		item	1	0.043
catheter, suction		item	1	0.620
dressing, 4in x 4.75in (Tegaderm)		item	1	1.771
electrode, ECG (single)		item	3	0.090
electrode, ground		item	1	0.445
gas, oxygen		liter	200	0.003
gauze, sterile 4in x 4in		item	4	0.159
gloves, sterile		pair	1	0.840
gown, surgical, sterile		item	1	4.671
iv infusion set		item	1	1.112
kit, iv starter		kit	1	1.368
oxygen mask (1) and tubing (7ft)		item	1	0.963
pulse oximeter sensor probe wrap		item	1	0.617
stop cock, 3-way		item	1	1.175
swab-pad, alcohol		item	2	0.013
syringe 1ml		item	1	0.140
syringe-needle 3ml 22-26g		item	2	0.160

tape, surgical paper 1in (Micropore)	inch	12	0.002
tourniquet, non-latex 1in x 18in	item	1	0.226

Equipment: Updated January 2014

EF027	table, instrument, mobile
EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)
EQ032	IV infusion pump
EF018*	Stretcher**

*indicates additional equipment added to recommendation in January 2014

Scenarios for stretcher use:

- **Consistent use throughout procedure – patient is wheeled in on the stretcher and remains on the stretcher for the entirety of the procedure. Patient recovers on the stretcher.**
- **Short procedure, cannot be used by another patient – patient is wheeled in on the stretcher, but is moved for the procedure. The stretcher remains with the patient and the patient recovers on the stretcher.**
- **Long procedure, can be used by another patient – patient is wheeled in on the stretcher, but is moved for the procedure. The linens are changed and the stretcher can be used for other patients. Patient recovers on a different stretcher.**

**Although the other equipment items in the standard package, table, instrument, mobile (EF027), ECG, 3-channel (with SpO2, NIBP, temp, resp) (EQ011) and IV infusion pump (EQ032), would typically have the same number of minutes, equipment time for the stretcher should be based on the typical scenario for the service.

Contrast Imaging Workgroup **Approved October 2013**

The Workgroup reviewed the standard package and agreed that the listed supplies are routinely used in enhanced contrast imaging services. In addition, the Workgroup discussed potential overlap with the IV Starter Kit and it was clarified that the IV is started first and then the contrast is injected, meaning the events occur at different times. The Workgroup agreed to add to the IV Starter Kit an *underpad 2ft x 3ft (Chux)* (SB044). Finally, the PE Subcommittee and specialty societies agreed that this standard package would also extend to CT & MR angiography studies, with the addition of a stop cock (SC050) and additional tubing.

The Practice Expense Subcommittee submits the following recommendations:

Standard Supply Package for CT and MRI codes with contrast enhanced imaging

Imaging w/Contrast - Standard Package			
MEDICAL SUPPLIES	**CODE**	**UNIT**	**QUANTITY**
kit, iv starter	SA019	kit	**1**
gloves, non-sterile	SB022	pair	**1**
angiocatheter 14g-24g	SC001	item	**1**
heparin lock	SC012	item	**1**
iv tubing (extension)	SC019	foot	**3**
needle, 18-27g	SC029	item	**1**
syringe 20ml	SC053	item	**1**
sodium chloride 0.9% inj bacteriostatic (30ml uou)	SH068	item	**1**
swab-pad, alcohol	SJ053	item	**1**

Revisions to the IV Starter Kit – adding supply code (SB044) underpad 2ft x 3ft (Chux)

IV Starter Kit
1 tourniquet
1 alcohol prep pad
1 PVP ointment
1 PVP prep pad
2 gauze sponges (2"x2")
1 bandage (1"x3")
1 sm roll surgical tape
1 pr gloves
1 underpad 2ft x 3ft (Chux)

Practice Expense Subcommittee
Staff Note

Endoscope Cleaning and Disinfecting Pack, SA042

In January 2012, the PE Subcommittee noted that the pack included in supplies for cleaning the endoscope, CMS supply item SA042, includes gluteraldehyde (disinfecting/sanitizing agent) and does not contain a basin for the glueraldehyde. American Society for Gastrointestinal Endoscopy recommends that the irrigation basin, CMS code SJ009, be added to the pack below.

DESCRIPTION	Code	Unit	Item Qty	Unit price
pack, cleaning and disinfecting, endoscope	**SA042**	**pack**		**15.520**
gloves, non-sterile		pair	4	0.084
gown, staff, impervious		item	1	1.186
face shield, splash protection		item	1	1.706
biohazard bag		item	1	0.062
gauze, sterile 4in x 4in (10 pack uou)		item	1	0.798
alcohol isopropyl 70%		ml	60	0.002
cleaning brush, endoscope		item	1	4.992
glutaraldehyde 3.4% (Cidex, Maxicide, Wavicide)		oz	32	0.165
glutaraldehyde test strips (Cidex, Metrex)		item	1	1.012

November 22, 2013

Scott Manaker, MD
Chair, Practice Expense Subcommittee
The American Medical Association (AMA)
330 North Wabash Ave., Suite 39300
Chicago IL 60611-5885

Dear Dr. Manaker,

Thank you for the opportunity to submit additional comments on the post procedure monitoring issues that have been discussed by the RUC's practice expense subcommittee. Specifically the moderation sedation workgroup asked our multispecialty group to comment on the following 4 issues:

1. The necessity for the clinical staff type to be RN rather than a blend for post-procedure following recovery from moderate sedation.
2. Relevant regulations from multiple states (2 or 3), which represent the typical scenario across the country.
3. Determination of whether or not the diameter of the access (size French) is correlated to the duration of the monitoring time.
4. Whether the use of a percutaneous closure device has an effect on the duration of the monitoring time.

This multispecialty expert panel has reviewed the issues posed by the PE subcommittee and has attached documentation to support our consensus recommendations. We believe our original recommendations submitted for the September 2013 RUC meeting, are supported by leading clinical experts, national standard practices and industry documentation. We believe the following standards should be established:

Arterial
All arterial access procedures have a MINIMUM of 4 hours post procedure recovery time as per standard national protocol. An RN is floating amongst 4 patients for a total of 15 minutes spent per hour. That is a total of 60 minutes. Fifteen minutes of the RN time will now be allocated to "post-procedure moderate sedation monitoring time" for the first hour of post recovery. Forty-five minutes will now be allocated to "post-procedure [other] monitoring time" for the 2nd through 4th hour of recovery.

Venous
All venous access procedures have a MINIMUM of 2 hours post procedure recovery time as per standard national protocol. An RN is floating amongst 4 patients for a total of 15 minutes spent per hour. That is a total of 30 minutes. Fifteen minutes of RN time will now be allocated to "post-procedure moderate sedation monitoring time" for the first hour of post recovery. The remaining fifteen minutes will be allocated to "post-procedure [other] monitoring time" for the 2nd hour of recovery.

Dialysis

Dialysis AV graft diagnostic procedures require a MINIMUM of 2 hours post procedure recovery to assess for bleeding from access sites in a high pressure circuit following use of large sheaths for access. An RN is floating amongst 4 patients for a total of 15 minutes spent per hour. That is a total of 30 minutes. Fifteen minutes of RN time is allocated to "post-procedure moderate sedation monitoring time" for the 1st hour. The remaining 15 minutes of RN time will be allocated to the "post-procedure [other] monitoring time" for the 2nd hour of recovery.

Our multispecialty expert panel believes the above recommendations are national standards and followed by the typical practice. Below we provide additional support for our recommendations.

The necessity for the clinical staff type to be RN rather than a blend for post-procedure following recovery from moderate sedation.

The RUC would like to change the standard for post procedure monitoring (after the first hour of CS monitoring) from an RN to a nurse blend. We have not found documentation to prove this change is warranted. On the contrary, we have found several sources that support continuing the use of RN for post procedure monitoring.

For example, Florida law states that a minimum of an RN must be used for monitoring and supervising the recovery of a patient. The law also goes on to state that licensed health care providers are required to monitor the recovery of a patient who has been given anesthesia. A physician, osteopathic physician, physician assistant (PA), or a licensed registered nurse (RN) with post-anesthesia training and experience must be available.
http://www.doh.state.fl.us/mqa/medical/osr_faq.html

California's historic first-in-the-nation safe staffing ratios, sponsored by the California Nurses Association, took 13 years to win and have been in effect since January 2004. This legislation requires RNs to monitor the post anesthesia recovery units. There is an active movement to establish these protocols on a nation level:

- **RNs Welcome Introduction of House Bill to Set Safe RN-to-Patient Staffing Ratios in Every Hospital** *National Nurses United* Press Release, 5/9/13
- **HR 1907, the Safe Nurse Staffing for Patient Safety and Quality Care Act** establishes minimum RN ratios for every hospital unit at all times.
- **The bill complements Senate legislation, S 739**, recently re-introduced by California Sen. Barbara Boxer. Both bills are modeled on a California law that studies have documented has saved patient lives, improved the quality of care in multiple other ways, and reduced nurse burnout keeping the most experienced RNs at the patient bedside.

The scope of practice for the LPN often precludes them from independently monitoring post anesthesia care patients. http://www.cphcs.ca.gov

We believe there is ample documentation to establish that an RN is the appropriate staff type to monitor post anesthesia patients.

Relevant regulations from multiple states (2 or 3), which represent the typical scenario across the country.

The RUC has inquired about the typicality of individual state laws regarding scope of practice. We have included citations for state laws from CA and FL on these issues. These are the two states with the highest number of Medicare beneficiaries (CA and FL). We believe it is representative of the practices in other states.

Determination of whether or not the diameter of the access (size French) is correlated to the duration of the monitoring time.

The RUC/PE subcommittee queried us about a possible correlation of access size to the duration of the monitoring time. While we agree there is a relationship between access size and monitoring, we do not believe there is a prescriptive/prospective formula that can be applied to all procedures. In the attached Quality Improvement Guidelines (QI) (Attached) they state, "The duration of this period of bed rest will depend on the site and size of the venotomy and the patient's medical condition". We believe the PE subcommittee should rely on the consensus recommendations of the specialties providing the service to establish the post procedure monitoring time for each procedure, as they come before the RUC.

Whether the use of a percutaneous closure device has an effect on the duration of the monitoring time.

The RUC/PE subcommittee also queried us about the role a percutaneous closure device has on the post procedure monitoring time. As stated above, we believe there is a relationship but we do not believe there is a prescriptive/prospective formula that can be applied to all procedures. The FDA's instructions for use for closure devices discuss post procedure monitoring. The instructions for use clearly leave the decision making to the treatment physician, as there is not a "one size fits all" protocol for post procedure monitoring of patients. Our recommendation for four hours of post procedure monitoring takes into account the use of a closure device.

Other Issues

The RUC has established a post procedure-monitoring standard of 1:4. This issue was not opened for discussion and comment, however, we stress that there are several sources that document the true ratio in practice is 1:2 or 1:3. They include, FL law, CA law and AHRQ. We submitted a letter to the RUC requesting this issue be opened for further discussion (submitted XX). We believe the overwhelming documentation outlining a more conservative ratio is more than enough to at least support our recommendation.

In addition to the staff ratio issue, the issue of "duration" remains an open issue. The RUC would like to make one-hour post procedure monitoring (post CS monitoring) the standard. That is just not the typical practice. It is unsafe. We are supporting documentation here for several procedures that talk about 'six hours' of post procedure monitoring. Again, we are not asking the RUC to go above the recommendations we submitted, but these references more than support our recommendations that span from 1 to 4 hours.

Conclusion
In conclusion, we appreciate the AMA allowing us to submit additional documentation to support our MS recommendations for several codes at the last RUC meeting. We believe the citations and documentation outlined here more than supports our recommendations. As such, we request that (1) the RUC adopt the recommendations we submitted to the PE subcommittee for the MS exercise and (2) accept our standards for the interventional procedures.

We look forward to discussing these with you further. Please let us know if you have any questions.

Regards,

The Society of Interventional Radiology (SIR)
The Society for Vascular Surgery (SVS)
The American College of Radiology (ACR)
The American College of Cardiology (ACC)
The Society for Cardiovascular Angiography and Interventions (SCAI)
The Renal Physician Association (RPA)

Table 147. **Medicare--Enrollment by State and Other Areas: 2000 to 2009**
[In thousands (39,620 represents 39,620,000). Hospital (HI) and/or supplementary medical insurance (SMI) enrollme
July 1]

State and Area	2000	2001	2002	2003	2004	2005	2006	2007	2008
All areas \1	**39,620**	**40,026**	**40,489**	**41,087**	**41,729**	**42,395**	**43,314**	**44,263**	**45,412**
United States	**38,762**	**39,149**	**39,594**	**40,173**	**40,792**	**41,003**	**42,020**	**43,259**	**44,385**
Alabama	685	695	706	719	733	740	766	789	809
Alaska	42	44	46	48	50	51	54	57	60
Arizona	675	691	708	729	755	777	805	841	870
Arkansas	439	442	446	453	460	464	480	496	509
California	3,901	3,955	4,009	4,078	4,150	4,158	4,241	4,369	4,492
Colorado	467	476	484	493	506	513	533	558	579
Connecticut	515	516	518	522	524	520	527	537	549
Delaware	112	114	116	119	123	125	130	136	141
District of Columbia	75	75	74	74	73	72	73	74	75
Florida	2,804	2,838	2,876	2,921	2,982	3,008	3,064	3,133	3,212
Georgia	916	933	951	974	998	1,016	1,063	1,111	1,153
Hawaii	165	168	171	175	178	180	184	189	194
Idaho	165	169	173	178	184	188	196	207	214
Illinois	1,635	1,640	1,646	1,661	1,676	1,674	1,702	1,741	1,775
Indiana	852	858	865	878	889	893	915	941	964
Iowa	477	478	479	482	486	484	491	500	506
Kansas	390	391	392	394	397	397	403	412	418
Kentucky	623	630	637	648	660	668	689	711	728
Louisiana	602	605	612	620	627	630	616	639	656
Maine	216	219	223	227	231	233	238	247	253
Maryland	645	655	664	674	685	687	704	723	745
Massachusetts	961	961	963	966	968	961	976	997	1,019
Michigan	1,403	1,414	1,426	1,445	1,464	1,468	1,502	1,541	1,580
Minnesota	654	660	667	676	686	691	708	729	749
Mississippi	419	423	429	437	446	449	459	469	479
Missouri	861	867	874	884	896	901	922	946	966
Montana	137	138	140	142	145	146	150	156	160
Nebraska	254	255	256	257	259	259	263	268	271
Nevada	240	251	261	274	286	294	304	318	330
New Hampshire	170	173	176	180	183	185	191	204	212
New Jersey	1,203	1,208	1,213	1,220	1,225	1,215	1,236	1,257	1,283
New Mexico	234	238	244	250	257	261	273	285	294
New York	2,715	2,729	2,747	2,763	2,775	2,758	2,796	2,841	2,891
North Carolina	1,133	1,155	1,178	1,205	1,235	1,255	1,300	1,359	1,405
North Dakota	103	103	103	103	103	103	104	105	107
Ohio	1,701	1,705	1,713	1,727	1,739	1,731	1,766	1,805	1,841
Oklahoma	508	511	515	521	529	531	549	565	578
Oregon	489	496	504	513	527	532	547	567	584
Pennsylvania	2,095	2,095	2,101	2,110	2,118	2,108	2,144	2,184	2,221
Rhode Island	172	172	172	172	173	171	173	175	178
South Carolina	568	580	592	606	624	637	664	697	724
South Dakota	119	120	121	122	123	123	126	129	132
Tennessee	829	842	855	872	891	903	938	975	1,004
Texas	2,265	2,300	2,338	2,390	2,451	2,491	2,598	2,708	2,802
Utah	206	210	215	220	227	231	242	254	264
Vermont	89	90	91	93	94	95	98	102	105
Virginia	893	910	927	946	967	981	1,011	1,045	1,079
Washington	736	746	759	775	799	807	837	873	903
West Virginia	338	340	343	347	351	351	359	367	373
Wisconsin	783	787	794	804	814	818	835	854	874
Wyoming	65	66	67	69	70	70	72	74	76
Outlying areas \2	537	550	562	575	613	622	633	(NA)	(NA)
Pending State Designation \3	321	327	333	340	324	769	660	(NA)	(NA)

SYMBOL:
NA Not available.
FOOTNOTES:

\1 Includes outlying areas and pending state designation.

\2 Includes American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Marianas, Puerto Ric Virgin Islands, and Wake Island.

\3 Include foreign countries and unknown places of residence.

Source: U.S. Centers for Medicare and Medicaid Services, "Medicare Beneficiaries enrolled as of July 1 of each ye Years 1995-1998", Medicare Enrollment Reports; Data Compendium.

For more information:
http://www.cms.hhs.gov/researchers/statsdata.asp
http://www.cms.gov/DataCompendium/

Quality Improvement Guidelines for the Performance of Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism

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ABBREVIATIONS

DVT = deep vein thrombosis, IVC = inferior vena cava, PE = pulmonary embolism

PREAMBLE

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such they represent a valid broad expert constituency of the subject matter under consideration for standards production.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

METHODOLOGY

SIR produces its Standards of Practice documents using the following process. Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned dependent upon the magnitude of the project.

An in-depth literature search is performed by using electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members by using a Modified Delphi Consensus Method (Appendix A). For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Revisions Subcommittee members of the Standards of Practice Committee, either by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Subcommittee, and appropriate revisions made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

INTRODUCTION

This guideline was revised by the American College of Radiology (ACR) in collaboration with SIR.

These guidelines are written to be used in quality improvement programs to assess inferior vena cava (IVC) filter placement procedures. The most important processes of care are (i) patient selection, (ii) performing the procedure, and (iii) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

Pulmonary embolism (PE) continues to be a major cause of morbidity and mortality in the United States. Estimates of the incidence of nonfatal PE range from 400,000 to 630,000 cases per year, and 50,000 to 200,000 fatalities per year are directly attributable to PE (1–4). The current preferred treatment for deep vein thrombosis (DVT) and PE is anticoagulation. However, as many as 20% of these patients will have recurrent PE despite adequate anticoagulation (3,5,6).

Interruption of the IVC for the prevention of PE was first performed in 1893 by using surgical ligation (7). Over the years, surgical interruption took many forms (ligation, plication, clipping, or stapling), but IVC thrombosis was a frequent complication after these procedures. Endovascular approaches to IVC interruption became a reality in 1967 after the introduction of the Mobin-Uddin filter (8).

Many devices have since been developed for endoluminal caval interruption, and currently several devices designed for permanent placements are commercially available in the United States. In addition to

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permanent IVC filters, retrievable IVC filters are also available. These filters can be left in place as a permanent implant but also can be removed when the indication for filter placement resolves. (Detailed information regarding each of these filters can be found in several reviews [9–23].) Selection of a device requires knowledge of the clinical settings in which filters are used, as well as an evaluation of the clot-trapping efficiency and structural integrity of the device, the occlusion rate of the IVC and access vein, the risk of filter movement and filter embolization, magnetic resonance (MR) imaging compatibility of the device, and the ease of placement.

Placement of a caval filter can be performed as an outpatient or inpatient procedure. Practically speaking, however, most filter placements will occur in the inpatient population because of ongoing medical therapy for acute thromboembolic disease or underlying illness.

The IVC should be assessed with imaging before placement of a filter, and the current preferred method is by vena cavography. Before filter selection and placement, the length and diameter of the infrarenal IVC should be assessed, the location and number of renal veins determined, IVC anomalies defined (eg, duplication), and intrinsic IVC disease such as preexisting thrombus or extrinsic compression excluded. If available, earlier imaging studies (eg, contrast-enhanced computed tomography [CT] or MR imaging of the abdomen) may be used to evaluate the anatomy of the IVC (ie, size, patency, and anatomic variants). The ideal location for filter placement for preventing lower-extremity and pelvic venous thromboembolism is the infrarenal IVC. The apex or superior aspect of any filtration device should be at or immediately inferior to the level of the renal veins according to the manufacturer's recommendations. In specific clinical circumstances, other target locations may be appropriate.

Placement of a caval filter is commonly accomplished through right femoral or right internal jugular vein approaches; however, other peripheral (eg, antecubital vein) and central venous access sites can be used. Filters can be placed in veins other than the IVC to prevent thromboembolism (an off-label indication). Implant sites have included iliac veins, subclavian veins, superior vena cava, and IVC (suprarenal and infrarenal). This report provides quality improvement guidelines only for filter placement within the IVC because of the limited data available for implantation sites other than the IVC. The patient's clinical condition, the type of filter available, the available access sites, and the expertise of the treating physician should always be considered when the decision to place an IVC filter has been made.

IVC filters labeled as retrievable by the United States Food and Drug Administration are also labeled for permanent placement. Retrievable filters may be placed with the intent of either temporary or permanent filtration. Removal of retrievable IVC filters may be accomplished in those cases in which the indication was for prophylaxis and prevention of PE with temporary contraindication to anticoagulation. Filters placed with the intent of subsequent retrieval may be left in place permanently for any of several reasons (eg, continuing need for filtration, thrombus on the filter, inability to retrieve the filter). Data for the feasibility of filter retrieval vary widely among devices and centers. Filters that are not retrieved function as permanent filters.

Definitions

For the purpose of this guideline, the following definitions apply (24,25):

Permanent placement. Permanent placement is deployment in those situations in which lifelong protection against thromboembolic episodes is needed.

Temporary placement. Temporary placement is deployment in those situations in which time-limited protection against thromboembolic episodes is needed.

Procedural success. Procedural success is the deployment of a filter such that the filter is judged suitable for mechanical protection against PE.

Recurrent PE. Recurrent PE is PE that occurs after filter placement and is documented by pulmonary arteriography, cross-sectional imaging, or significant change in ventilation/perfusion lung scan indicative of recurrent PE, or at autopsy.

IVC thrombotic occlusion. IVC thrombotic occlusion is the presence of an occluding thrombus in the IVC after filter insertion and documented by ultrasound (US), CT, MR imaging, venography, or autopsy; this may be symptomatic or asymptomatic.

IVC penetration. IVC penetration is penetration of the vein wall by a filter strut or anchor device with transmural incorporation. For quality improvement reporting purposes, the definition of IVC penetration is filter strut or anchor devices extending more than 3 mm outside the wall of the IVC as demonstrated by CT or venography, or at autopsy. Acute penetration occurring during placement of the filter is considered an insertion problem (as detailed later).

Filter embolization. Filter embolization is postdeployment movement of the filter or its components to a distant anatomic site completely out of the target zone.

Filter movement. Filter movement is a change in filter position compared with its deployed position (cranial or caudal) of more than 2 cm as documented by plain radiography, CT, or venography.

Filter fracture. Filter fracture is any loss of a filter's structural integrity (ie, breakage or separation) documented by imaging or at autopsy.

Insertion problems. Insertion problems refer to malfunctions of the filter or deployment system such as incomplete filter opening, filter tilt more than 15° from the IVC axis (eg, non–self-centering filters), misplacement of filter outside the infrarenal IVC when the operator's intent is to place the filter in the infrarenal IVC (eg, when a portion of the filter is within one iliac vein), or prolapse of filter components. Filter malposition requiring surgical/endovascular removal is considered an insertion problem complication.

Access site thrombus. Access site thrombus refers to occlusive or nonocclusive thrombus developing at the venotomy site after filter insertion, and documented by US or other imaging.

Access site complications with clinical sequelae. Access site complications with clinical sequelae include arteriovenous fistula, hematoma, or bleeding requiring a transfusion, hospitalization (admission or extended stay), or further treatment.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; Appendix B). The complication rates and thresholds herein refer to major complications unless otherwise specified.

INDICATIONS

Therapeutic (Documented Thromboembolic Disease)

IVC filter placement has a therapeutic indication (ie, in cases of documented thromboembolic disease) in patients with evidence of PE or IVC, iliac, or femoropopliteal DVT and one or more of the following:

- Absolute or relative contraindication to anticoagulation;
- Complication of anticoagulation;
- Failure of anticoagulation;
- Recurrent PE despite adequate therapy;
- Inability to achieve/maintain adequate anticoagulation;
- Propagation/progression of DVT during therapeutic anticoagulation;
- Massive PE with residual DVT in a patient at risk for further PE;
- Free-floating iliofemoral or IVC thrombus; and

- Severe cardiopulmonary disease and DVT (eg, cor pulmonale with pulmonary hypertension) (24–31).

Prophylactic (No Current Thromboembolic Disease)

IVC filter placement has a prophylactic indication (ie, in cases without current thromboembolic disease) in the following settings:

- Severe trauma without documented PE or DVT;
- Closed head injury;
- Spinal cord injury;
- Multiple long-bone or pelvic fractures; and
- Patients at high risk (eg, immobilized or in an intensive care unit) (24–31).

Suprarenal Filter Placement

Suprarenal caval filter placement may be considered when any of the following situations exist in addition to the indications listed earlier.

1. Presence of IVC thrombus precluding placement of a filter in the infrarenal IVC;
2. Filter placement during pregnancy (suprarenal placement is also appropriate in women of childbearing age);
3. Thrombus extending above previously placed infrarenal filter;
4. Gonadal vein thrombosis;
5. Anatomic variants, eg, duplication of the IVC, low insertion of renal veins;
6. Significant extrinsic compression of the infrarenal IVC;
7. Intrinsic narrowing of the infrarenal IVC; and
8. Intraabdominal or pelvic mass in patients who will undergo surgery and in whom operative IVC mobilization is contemplated.

The IVC should be assessed with imaging before placement of a filter. The current preferred method is by vena cavography. Before filter selection and placement, the length and diameter of the suprarenal IVC should be assessed, the location and number of renal veins determined, the location and number of hepatic veins determined, the right atrium identified, IVC anomalies (eg, duplication) defined, and intrinsic IVC disease, such as preexisting thrombus or extrinsic compression, excluded. If available, previous imaging studies (eg, contrast-enhanced CT or MR imaging of the abdomen) may be used to evaluate the anatomy of the IVC (ie, size, patency, and anatomic variants). The anatomic considerations should be used in the final planning for filter placement and choice of device.

Filters Placed for Temporary Use and Possible Future Retrieval

Placement of filters for temporary use and possible future retrieval may be considered when any of the following situations exist in addition to the indications listed earlier.

1. PE and/or DVT and transient inability to anticoagulate;
2. Prophylactic prevention of PE in patients at high risk; and
3. The use of retrievable filters should also be considered in pediatric and young adult patients, as the long-term effects and durability of the devices are not precisely known. Currently, there are no filters specifically designed for use in children. The safety and efficacy of vena cava filters in children have not been firmly established. Case reports and series have described the placement and removal of filters in children, but their long-term effect is unclear (32).

The threshold for these indications is 95%. When fewer than 95% of procedures are performed for these indications, the process of patient selection should be reviewed according to institutional policy.

RELATIVE CONTRAINDICATIONS

Relative contraindications to IVC filter placement in this setting are (i) uncorrectable severe coagulopathy and (ii) bacteremia or untreated infection. Clinical judgment should be applied in these situations, weighing the theoretical risk of implant infection versus the risk of PE.

SPECIFICATIONS OF THE EXAMINATION

There are several technical requirements to ensure safe and successful filter placement procedures. These include adequate angiographic equipment and institutional facilities, physiologic monitoring equipment, and support personnel.

Equipment and Facilities for Filter Placement

The following are considered the minimum equipment requirements for performing vena cavograms and filter placement. In planning facilities for IVC placement, equipment and facilities more advanced than those outlined here may be desired to produce higher-quality studies with reduced risk and time of study.

The facility should include, at a minimum:

1. A high-resolution image receptor, preferably with a 28–40-cm field of view, and an imaging chain with standard angiographic filming capabilities including serial 14-inch film changers or (preferably) a digital imaging system with a minimum 1,024-image matrix. Digital angiographic systems are preferred, as they allow for reduced volumes of contrast material and reduced examination times. Images are acquired and stored on conventional film or digitally on computerized storage media. Imaging and image recording must be consistent with the "As Low As Reasonably Achievable" radiation safety guidelines. The use of cineradiography or small-field mobile image intensifiers is inappropriate for the routine recording of the vena cavogram and IVC placement, because these methods cause an unacceptably high patient and operator radiation dose. Use of last image-hold and pulsed fluoroscopy are recommended for dose reduction;
2. Adequate angiographic supplies such as catheters, guide wires, needles, and introducer sheaths;
3. An angiographic injector capable of varying injection volumes and rates with appropriate safety mechanisms to prevent overinjection;
4. An angiography suite that is large enough to allow easy transfer of the patient from the bed to the table and allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions; and
5. An area within the institution appropriate for patient preparation before the procedure and for observation of patients after the procedure. This might be within the radiology department, a short-stay unit, a routine nursing unit, or a postanesthesia care unit. At this location, there should be personnel to provide care as outlined later in the Patient Care section, and there should be immediate access to emergency resuscitation equipment.

Physiologic Monitoring and Resuscitation Equipment

1. Equipment should be present in the procedure suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities that use moderate sedation, a pulse oximeter monitor should be available, as outlined in the Practice Guideline for Sedation/Analgesia (33).
2. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be maintained and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

Support Personnel

Radiologic technologists properly trained in the use of the angiographic equipment should assist in performing and imaging the procedure. They

should demonstrate appropriate knowledge of patient positioning, angiographic image recording, angiographic contrast agent injectors, angiographic supplies including IVC filters, and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. The technologist should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.

If the patient does not receive sedation for the procedure, one of the staff assisting the procedure should be assigned to periodically assess the patient's status. In cases in which moderate sedation is used in adults, light or moderate sedation is used in children, or the patient is critically ill, an experienced licensed provider should be present whose primary responsibility is monitoring the patient's vital signs, sedation state, and level of comfort/pain. This person should maintain a record of the patient's vital signs, the time and dose of medications given, and other pertinent information, as outlined in the Practice Guideline for Sedation/Analgesia (33).

Acute Care Support

Although surgical or other emergency treatment is needed infrequently for serious complications after filter placement procedures, there should be prompt access to surgical and interventional equipment and to specialists familiar with the management of patents with complications in the unlikely event of a life-threatening complication.

Patient Care

For additional information on patient care, see the Practice Guideline for Interventional Clinical Practice (34).

Preprocedure care. For elective filter placement, the following should be documented:

a. Clinically significant history, including indications for the procedure;
b. Clinically significant physical or diagnostic examination findings, including clinical or medical conditions that may necessitate specific care, such as preprocedure antibiotics and other measures;
c. Clinically indicated laboratory evaluation including, but not limited to, coagulation factors, creatinine, white blood cell count, and previously obtained cultures; and
d. Preprocedure documentation should conform to the requirements of the Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures (35).

Informed consent must be in compliance with all state laws and the ACR Practice Guideline on Informed Consent for Image-Guided Procedures (36).

For emergency procedures, a note should be written summarizing the indication for the study, the pertinent history and physical findings, if available, and the proposed procedure.

Procedural care. Adherence to the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery is required for procedures in non–operating room settings, including bedside procedures. "Time out" must be conducted in the location where the procedure will be done, just before starting the procedure and must:

- Involve the entire operative team;
- Use active communication; and
- Be briefly documented, such as in a checklist, and include at least:
  a. Correct patient identity;
  b. Correct side and site, if applicable;
  c. Agreement on the procedure to be done;
  d. Correct patient position; and
  e. Availability of correct implants and any special equipment or special requirements

The organization should have processes and systems in place for reconciling differences in staff responses during the time out.

All patients should have cardiac monitoring continuously during the procedure with intermittent blood pressure monitoring. A record of vital signs should be maintained.

All patients should have intravenous access for the administration of fluids and medications as needed.

If the patient is to receive sedation for the procedure, pulse oximetry should be used. A registered nurse or other appropriately trained personnel should be present, and his/her primary responsibility should be to monitor the patient. A record should be kept of medication doses and times of administration. The Practice Guideline for Sedation/Analgesia contains further information (33).

Postprocedure care. All patients should be in bed rest and observed in the initial postprocedure period. The duration of this period of bed rest will depend on the site and size of the venotomy and the patient's medical condition.

During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site.

Initial ambulation of the patient must be carefully supervised. The puncture site stability and independent patient function and mobility must be assured.

The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If conscious sedation was administered before and during the procedure, complete recovery from sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician or a nurse. The Practice Guideline for Sedation/Analgesia contains further recommendations (33).

Selection Criteria for Short-term Observation

The duration of postprocedure observation must be individualized. IVC filter placement can be performed on some patients with a short period of postprocedure observation (< 6 h) before discharge to home; others require overnight care. Short-term observation should only be considered when all the following conditions can be met:

1. Those patients capable of independent ambulation before the procedure demonstrate stable independent ambulation after the procedure. Nonambulatory patients have adequate assistance after discharge to provide care as needed.
2. The patient is capable of following instructions and detecting changes in symptomatology. Alternatively, patients with impaired mental or neurologic status should have adequate assistance after discharge to provide care as needed.
3. The patient is provided with instructions on how to recognize potential complications and how to obtain medical assistance in the event of such complications. A responsible adult is also provided with information regarding recognition of potential complications and is available to transport the patient and be in attendance during the initial night after discharge.
4. The patient is free of concurrent serious medical illness that might contribute to a significantly increased risk of complication.
5. The patient has recovered from the effects of sedation.

Relative Contraindications to Short-term Observation

Several factors must be considered when determining the length of postprocedure skilled nursing care. Some of the relative contraindications to short-term observation are as follows:

1. Patients with significant risk of contrast media–associated nephrotoxicity that might be prevented by hospitalization and intravenous hydration.
2. Patients with coagulopathies or electrolyte abnormalities that require correction should be hospitalized until stable.
3. Insulin-dependent diabetic patients who have labile serum glucose levels in the periprocedural period should be hospitalized until in stable condition.
4. Complications occurring during or after IVC filter placement, including large hematoma, anuria, and persistent nausea and vomiting should prompt observation until symptoms resolve.

5. Patients who exhibit hemodynamic instability or significant dysrhythmia during or after the procedure should be hospitalized until in stable condition.
6. Patients who live alone.
7. Patients with concurrent serious medical illness that might contribute to a significantly increased risk of complication should be hospitalized until in stable condition.
8. Patients with impaired mental or neurologic status who do not have adequate assistance to provide care as needed should be hospitalized until appropriate assistance is available or no longer required.

The decision for short-term or longer-term postprocedure observation must be individualized, and a patient's care may vary from the aforementioned criteria for sound clinical reasons. The decision in each case must be made by the physician who performed the procedure and the referring physician after review of all pertinent data.

DOCUMENTATION

Reporting should be in accordance with the Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures (35).

RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as As Low As Reasonably Achievable.

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with As Low As Reasonably Achievable, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index, or lateral width. The dose reduction devices that are available on imaging equipment should be active or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard (ACR Resolution 17, adopted in 2006, revised in 2009, resolution 11).

QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading "Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education" on the ACR Web page (*http://www.acr.org/guidelines*).

These data should be used in conjunction with the thresholds described in the subsequent section to assess filter placement procedural efficacy and complication rates, and to trigger institutional review when these thresholds are exceeded.

QUALITY IMPROVEMENT

Success Rates and Thresholds

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Thus indicator thresholds may be used to assess the efficacy of ongoing improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator that should prompt a review. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a minimum threshold, or when complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes, if necessary. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality improvement program needs.

It is expected that the technical success for percutaneously placed IVC filters will be 97% or better in experienced hands. Therefore, the proposed threshold for review of technical failures should be 3%.

Participation by the radiologist in patient follow-up is an integral part and will increase the success rate of the procedure. Close follow-up, with monitoring and management of patients who have undergone placement of IVC filters is appropriate for the radiologist.

Table 1. Reported Rates and Thresholds for Complications (7,24,37–54)

Complication	Reported Rate (%)	Threshold (%)
Death (7)	0.12	<1
Filter embolization (24,37–49)	0.1	1
Deployment outside target area (50–52)	1–9	0
Access site thrombosis/ occlusion (53,54)	3–10	3

Table 2. Reported Incidences of Trackable Adverse Events (2,7,10,12,13,24,43,53,55–72)

Event	Reported Rate (%)
IVC penetration*(7,24,55–59)	0–41
Filter movement*(7,10,12,24,56,60–63)	0–18
Filter fracture (24,43)	2–10
Recurrent PE (24,56,61,53–65)	0.5–6
Access site thrombus, all types (7,53,64,65)	0–25
IVC occlusion (13,24,42,55,56,59,62,63,68)	2–30
Insertion problems (7,24,43,56,51–63,65,67,69,70)	5–23
Other complications (2,71,72)	1–15

* Clinically significant penetration and movement are believed to be rare. The rate of clinically significant penetration has been reported to be 0.4% (72), but is not precisely defined in the literature.

Complication Rates and Thresholds

Complications. Each currently available filter has been extensively studied as part of the Food and Drug Administration approval process. Few comparative studies have been completed to evaluate all filters in one project, and those that have done so have been retrospective analyses. Complication rates are highly variable depending on the filter being studied. For simplicity, these guidelines do not suggest threshold rates for each individual filter; rather, filtration devices are considered as a group (**Table 1**) (7,24,37–54).

Published rates for individual types of complications are highly dependent on patient selection and are, in some cases, based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient volume (eg, early in a quality improvement program).

Other trackable events. Because an IVC filter may be implanted as a permanent device (if not retrieved) and can be used in relatively young patients, several other trackable parameters when observed are appropriate to record in a quality improvement program. The events listed in **Table 2** (2,7,10,12,13,24,43,53,55–72) may or may not be clinically significant in a particular patient. For this reason, thresholds for these events are not included in this document.

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APPENDIX A: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

A. Require no therapy, result in no consequence.
B. Require nominal therapy, result in no consequence; includes overnight admission ($\geq$ 23 h) for observation only.

Major Complications

C. Require therapy, minor hospitalization ($\geq$ 24 h but $<$ 48 h).
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization ($>$ 48 h).
E. Result in permanent adverse sequelae.
F. Result in death.

APPENDIX B: CONSENSUS METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee members' practices, and, when available, the SIR HI-IQ System national database.

Consensus on statements in this document was obtained utilizing a modified Delphi technique (1,2).

The Committee was unable to reach consensus on the following:

1. Indication, efficacy, or complication threshold.
2. Indication, efficacy, or complication threshold.

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SIR DISCLAIMER

SIR Disclaimer The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

OSF
SAINT FRANCIS MEDICAL CENTER
Interventional Radiology

Inferior Vena Cava Filter Placement
Interventional Radiology

What is an inferior vena cava (IVC) filter?

- It is a filter that is placed in the inferior vena cava, which is a large vein that connects your leg veins with your heart.
- The IVC filter traps blood clots.

Why do I need an IVC filter?

- Sometimes, clots develop in the veins in your legs called deep vein thrombosis.
- A clot, or a piece of it, can move out of your leg and flow towards your heart and lungs.
- Clots in the lung can be life-threatening.
- The filter protects the lungs from these life-threatening clots.

Where is the IVC filter placement performed?

- It is performed in the Interventional Radiology Department.

Who will perform the IVC filter placement?

- One of our specially trained interventional radiologists.

What can I expect before the IVC filter placement?

- You will see one of our doctors and/or nurse clinicians, who will obtain a health history, perform a brief physical exam, explain the procedure, and answer your questions.
- You will have blood drawn.
- You will have an IV (intravenous catheter) started if you do not have one already.
- You will sign a consent form.

What can I expect during the IVC filter placement?

- You will be attached to a monitor so that IV medicines can be given to relax you.
- Your hip or neck area will be cleaned with special soap.
- The skin over the hip or neck area will be numbed with a special medicine through a needle.
- After making a small incision, the doctor will insert a small tube into a vein.
- Through this tube, the doctor will insert the filter into the large vein (IVC) in your belly.
- Xray dye will be injected through the tube to check the placement of the filter.
- Once the filter is placed, it immediately begins filtering all the blood going to the lungs from the legs.
- The tube in your neck or hip will be removed and light pressure will be held until the bleeding has stopped.

What can I expect after the IVC filter is placed?

- You will be on bedrest for 4 hours after the filter is placed.
- You will return to your hospital room to continue to be observed.

What are the risks of having an IVC filter placed?

- Bleeding at the incision site.
- Infection at the incision site.
- Damage to the vein used to insert the filter.
- Complete clotting of the IVC filter.

What are the benefits of having an IVC filter placed?

- To protect your lungs from life threatening blood clots.

What are the alternatives to having an IVC filter placed?

- You could be treated with bedrest and blood thinning medication.

"form no. 113-2262 (4/01)"

FACTS ABOUT: Liver biopsy

Your health care team made this handout to prepare you for a liver biopsy. If you have any questions after reading it, feel free to speak with your nurse or doctor.

What is a liver biopsy?

A liver biopsy is a minor medical procedure in which a doctor uses a needle to remove a small piece (biopsy) of your liver. This liver specimen is examined under a microscope to establish whether liver disease is present and how severe it is.

The liver biopsy helps your doctor plan your care. The procedure is done with local anesthesia in a hospital bed. A small section of the specimen is saved for future study.

What should I do before the liver biopsy?

Two weeks before your liver biopsy

- Tell your doctor immediately if you take aspirin or any anti-inflammatory medications, such as Indocin (indomethacin), Daypro (oxiprosyn), Aleve (naproxen), Motrin (ibuprofen), Advil (ibuprofen), or even Pepto Bismol. These medications contain salicylate, which is like aspirin. Salicylate can make you bleed easily and may increase the chance that you will bleed after the biopsy.
- Carefully read the ingredients section of your medication labels to look for aspirin (salicylic acid) or ibuprofen (Advil, Motrin). *Avoid these medications for 2 weeks before your liver biopsy.* If you need a pain reliever, you can take acetaminophen (Tylenol), or ask your NIH doctor to prescribe something safe for you to take.
- If you are take an anticoagulant or blood-thinner (for example, coumadin, heparin, Lovenox, Plavix) please contact your NIH doctor for specific instructions.
- Each time you come to the Clinical Center as an inpatient or as an outpatient, always bring a list of the your medications and the doses you take.
- If you smoke and cannot stop for 2 weeks before the biopsy, ask your doctor to order a nicotine patch for you.

The day before the biopsy:

- Arrive on the inpatient unit no later than 11 a.m. unless otherwise directed.
- You will have blood drawn, urine tests, chest x-ray, and an electrocardiogram (ECKG: heart-tracing).

- An ultrasound of your abdomen and liver may take place the day before the biopsy or on the day of the biopsy.
- Your NIH doctor will explain what you can expect during the liver biopsy and as well as its benefits and risks. You will have plenty of time to ask questions. If you agree to the procedure, the doctor will ask you to sign a consent form.
- Starting at midnight the night before the procedure, you will need to fast. Fasting means that you should not eat or drink anything, including water.

What happens the day of the procedure?

The morning of your biopsy

- The nurse will awaken you to insert an intravenous catheter (I.V.) into your vein. An I.V. is a flexible plastic tube about the width of pencil lead and 1 inch long. It will be taped to your skin and will be used to give you medications or fluids during the procedure.

  Please allow the nurse to start the I.V. when she asks so that your procedure can begin on time.
- Fasting blood samples will be drawn.
- You will be asked for a urine specimen. You will also start a 24-hour urine collection
- You will have an abdominal ultrasound in the x-ray department (if one was not already done).
- Before the biopsy starts, we will ask you to empty your bladder and change into hospital gown.
- You may be asked to provide a stool specimen.

What happens during the procedure?

- To help you relax, the doctor may order a medication that the nurse will inject into a muscle.
- You will then be asked to lie flat on your back without a pillow in your hospital bed, You should extend your right arm above your head.
- At the bedside, the doctor will do a portable ultrasound to find the exact location of your liver.
- You may then be given medication through your I.V .to relax you more, but you will stay awake during the procedure.
- With a special antiseptic, the doctor will clean the skin over your liver (upper right side of the abdomen). He or she will then use a small needle to inject a local anesthetic under the skin to numb this area.
- *Do not touch this clean area during the preparation.*
- You will be asked to take a regular breath in, let it all the way out (exhale), and then hold your breath for a few seconds. The doctor may have you practice this breathing before the biopsy. The biopsy is completed while you

hold your breath. The biopsy itself takes less than a second to perform.

- The doctor will get a sample of liver tissue by inserting a specially designed needle into the space between your ribs. He or she will rapidly move the needle in and out of the liver.
- A small dressing will be put over the biopsy site.

What happens after the biopsy?

Immediately after the biopsy

- You will be asked to turn onto your right side and stay in this position for 2 hours. This position puts pressure on the liver so that bleeding is less likely.
- We will monitor your blood pressure and pulse often.
- If you feel pain, nausea, dizziness, shortness of breath, or other discomforts, contact your nurse by pushing the nurse call button located on your bedrail.

  Some people feel discomfort in their right shoulder "referred pain"). Mild pain medication such as acetaminophen (Tylenol), usually relieves this discomfort.
- After 2 hours, the nurse will help you onto your back with the head of your bed raised 10 degrees (one pillow).
- Stay on bedrest for 6 hours
- Do not eat or drink for 3 hours after the biopsy. After 3 hours, you can have clear liquids.

Six 6 hours after the biopsy

- The nurse will take a blood sample from your I.V. or vein to check for complications.
- You may eat a regular diet.
- You should stay on bed rest with bathroom privileges until morning.

The morning after the biopsy

- You may shower and remove the dressing.
- You may put a small bandage on the biopsy site after your shower.
- Your doctor will examine you before discharge

What to do at home after the liver biopsy

1. Rest and stay at home ("home rest") after you are discharged from NIH. You may do limited activity.
2. Gradually return to normal activities. Lift nothing heavy (over 15 pounds) and do nothing strenuous for 4 days, After that, you may resume normal activities.
3. Shower or bathe as usual and change the bandage (if one was used) after showering. You do not need to cover the biopsy site after 24 hours.
4. Look at the biopsy site daily for 1 week. Notify your doctor if you notice:
   - increased redness
   - swelling

- bloody or pus-like drainage
- persistent shoulder, back, or abdomial pain

5. For pain or discomfort, take acetaminophen (regular strength Tylenol) as directed on the package. Do not take aspirin or non-steroidal anti-inflammatory drugs such as ibuprofen (Advil, Motrin) or naproxen (Aleve), for at least 7 days.

If you have other questions or concerns, call your doctor or nurse.

If you have severe pain or any sudden severe symptoms, call 911 for an ambulance and emergency care.

National Institutes of Health Clinical Center
Bethesda, MD 20892
Questions about the Clinical Center?
http://www.cc.nih.gov/comments.shtml

9/07

Guidelines on the use of liver biopsy in clinical practice

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Guidelines on the use of liver biopsy in clinical practice

A Grant, J Neuberger

1.0 Introduction

Erlich is credited with the first liver aspiration in 1883 and subsequently the first percutaneous liver biopsy for diagnostic purposes was reported in 1923.[1] The technique has been modified since then, and over the past 50 years it has become a central investigation of hepatic disease. The low mortality (0.01–0.17%) and the relatively low morbidity of this procedure have meant that liver biopsy has become widely used.[2]

Advances in medical technology and especially in imaging, together with advances in drug therapy have greatly influenced the diagnosis and management of hepatic disease and as a consequence the indications for liver biopsy are changing. In 1991 the British Society of Gastroenterology (BSG), together with the Royal College of Physicians of London, undertook a nationwide audit of percutaneous liver biopsy in 189 health districts.[3] It is clear from this audit and from reviewing the literature that there continue to be significant differences in clinical practice with respect to liver biopsy across the United Kingdom, and a lack of standardised protocols between institutions. These guidelines examine the evidence for methods of liver biopsy in adults.

2.0 Formulation of guidelines

2.1 VALIDITY AND GRADING OF RECOMMENDATIONS

The guidelines have been produced to conform with the North of England evidence-based guidelines development project.[4 5]

2.1.1 *Categories of evidence*

The strength of evidence used to formulate these guidelines was graded according to the following system:

Ia Evidence obtained from meta-analysis of randomised controlled trials.

Ib Evidence obtained from at least one randomised controlled trial.

IIa Evidence obtained from at least one well designed controlled study without randomisation.

IIb Evidence obtained from at least one other type of well designed, quasi-experimental study.

III Evidence obtained from well designed, non-experimental descriptive studies such as comparative studies, correlation studies and case studies.

IV Evidence obtained from expert committee reports or opinions or clinical experiences of respected authorities.

The evidence category is indicated after the citations in the reference section at the end of these guidelines.

2.1.2 *Grading of recommendations*

The strength of each recommendation is dependent on the category of the evidence supporting it, and is graded according to the following system:

A Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation (evidence categories Ia, Ib).

B Requires the availability of clinical studies without randomisation on the topic of recommendation (evidence categories IIa, IIb, III).

C Requires evidence from expert committee reports or opinions or clinical experience of respected authorities, in the absence of directly applicable clinical studies of good quality (evidence category IV).

2.2 SCHEDULED REVIEW OF GUIDELINES

As methods of diagnosis and tissue sampling change, new evidence will come to light and the content and evidence base for these guidelines should be reviewed frequently.

3.0 Types of liver biopsy

3.1 PERCUTANEOUS LIVER BIOPSY

Percutaneous liver biopsy may be classified according to the site of entry of the biopsy needle, whether the biopsy is performed in a blind or guided manner, or whether the biopsy track is plugged after the procedure.

3.1.1 *Transthoracic (transpleural or transparietal) and subcostal liver biopsy*

The patient lies supine for both of these approaches. The borders of the liver are usually defined by percussion or visualised by ultrasound. In most instances the intercostal space in the mid-axillary line just cephalad to the costal margin is then infiltrated with local anaesthetic, and a small incision is made through the dermis. The biopsy needle is then advanced into the intercostal space. The patient then holds his/her breath in expiration. The subsequent procedure for taking the biopsy then varies according to whether the biopsy needle is of the aspiration or cutting type.

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Abbreviations used in these guidelines: CT, computed tomography; MRI, magnetic resonance imaging; PBC, primary biliary cirrhosis; PSC, primary sclerosing cholangitis; ERCP, endoscopic retrograde cholangiopancreatography; GGT, γ-glutamyl transpeptidase; BT, bleeding time; INR, international normalised ratio; BSG, British Society of Gastroenterology; FFP, fresh frozen plasma; AMA, antimitochondrial antibody.

If the patient has an enlarged liver extending below the costal margin, then the site of entry of the biopsy needle may be subcostal. Complications are slightly more frequent with the transthoracic (4.1%) than the subcostal route (2.7%).[6]

After the biopsy procedure, the patient then lies on his/her right side or supine and pulse and blood pressure are monitored regularly in order to detect complications early (see section 7.10).

3.1.2 *Blind and guided liver biopsies*

A blind liver biopsy is one which is done as described earlier without imaging of the liver immediately prior to taking the biopsy sample.

A guided biopsy can be defined as a liver biopsy that is undertaken during real time imaging of the liver, whether that imaging modality be ultrasound, computed tomography (CT) or magnetic resonance imaging (MRI). Thus, guided biopsies should give access to thicker hepatic parenchyma, should avoid the puncture of adjacent organs, and should allow the accurate biopsy of focal hepatic lesions where appropriate. The use and evidence for image guided liver biopsy is controversial and will be discussed.

3.1.3 *Plugged liver biopsy*

Plugged liver biopsy is a modification of the percutaneous approach which was first described in 1984.[7 8] It has been advocated as an alternative method for obtaining liver tissue in patients with impaired coagulation where transjugular biopsy is not available.

In this technique a biopsy samples is taken using a Tru-cut needle in the conventional manner (see section 3.1.2) but only the obturator containing the specimen is removed leaving the outer cutting sheath within the liver substance. A plastic cannula is then inserted down the sheath and while the breath is still held in expiration, gelatin or gel foam is injected as the sheath is withdrawn.

3.2 TRANSVENOUS (TRANSJUGULAR) LIVER BIOPSY

Disorders of coagulation occur commonly in patients with liver disease and conventional practice in circumstances where there is significant disturbance of clotting is to avoid percutaneous liver biopsy because of the risk of bleeding, although the magnitude of this risk has not been defined in comparative studies.

Transvenous liver biopsy was first described in 1964[9]; this is usually done through a transjugular approach but may rarely be done via a transfemoral route. It is performed in a vascular catheterisation laboratory with videofluoroscopy equipment and cardiac monitoring because of the risk of cardiac arrhythmia as the catheter passes through the right atrium. The internal jugular vein is (usually) cannulated on the right side and a sheath inserted via a Seldinger technique. A 45 cm long catheter is then guided under fluoroscopic control through the right side of the heart to the inferior vena cava. The catheter is then loaded with the transvenous biopsy needle and advanced into the hepatic veins and the position checked by injection of contrast medium. The needle is then advanced rapidly 1–2 cm past the tip of the catheter with the patient holding his/her breath and the liver tissue is retained in the needle by aspiration on a syringe attached to the other end of the needle while it is inside the liver.

3.3 LAPAROSCOPIC LIVER BIOPSY

This technique is well established and its use varies widely between centres. In the United Kingdom it is often used for biopsying lesions found fortuitously at routine laparoscopic surgery. It has also been used in centres where access to transvenous liver biopsy is not available, for patients with abnormal clotting parameters, and also in patients who have a combination of a focal liver lesion and a coagulopathy where a histological diagnosis is essential in the management of that patient. Some centres in the USA perform laparoscopic liver biopsy on an outpatient basis[10] and in some Japanese centres more than 50% of liver biopsies are performed laparoscopically.[11]

The complications in laparoscopic liver biopsy include those of the laparoscopy itself.

4.0 Background

The indications for, and methods of liver biopsy have changed over the past few years[12] with the advent of new imaging techniques and the development of new indications for biopsy such as liver transplantation.[13] All invasive procedures have a mortality rate associated with them, and consequently the benefits of obtaining liver for histology should always be weighed against the possible morbidity and mortality of the procedure.

4.1 MORTALITY

The reported mortality from percutaneous liver biopsy varies considerably. This is partly because most of the larger series reporting liver biopsy complications have been retrospective.[14 15]

The overall mortality rate in the three months after liver biopsy has been reported to be as high as 19%.[3] Most of these deaths are the result of hepatic malignancy and advanced liver failure, and very few are due solely to the liver biopsy. The overall mortality rate also varies according to the centre in which the liver biopsies were performed—for example, in the Mayo Clinic the mortality from fatal haemorrhage after percutaneous biopsy was 0.11%,[16] whereas in an audit of liver biopsies performed in United Kingdom district general hospitals the death rate was between 0.13 and 0.33%.[3]

A generally accepted mortality rate in standard textbooks is between 0.1 and 0.01%.[2]

4.1.1 *Causes of mortality*

The main cause of mortality after percutaneous liver biopsy is intraperitoneal haemorrhage as shown in a retrospective Italian study of 68 000 percutaneous liver biopsies in which all six patients who died did so from intraperitoneal haemorrhage.[14] Three of these patients had had a laparotomy, and all had either cirrhosis or malignant disease, both of which

are risk factors for bleeding.[16 17] Other serious complications responded to treatment; puncture of viscera was never followed by serious clinical complications. Other series have shown, however, that puncture of the gall bladder followed by biliary peritonitis is a recognised cause of death.[3]

As the main source of mortality after percutaneous liver biopsy is haemorrhage, it is reasonable to assume that improvements in mortality rates can be made if the clinician understands the risk factors for bleeding, recognises bleeding promptly and aggressively resuscitates the patient. It has been suggested that patients with suspected biliary peritonitis should have an early laparotomy. It has also been suggested that patients who bleed significantly (i.e. patients whose haemoglobin falls to >20 g/l or who become haemodynamically unstable) should be considered for either laparotomy or therapeutic angiography if the bleeding does not stop with transfusion alone.[3]

4.2 MORBIDITY

The overall morbidity from percutaneous liver biopsy is difficult to ascertain as most studies are retrospective and therefore symptoms such as post-biopsy pain requiring simple analgesia are not recorded. Although many groups have studied complications, there is no consensus about the division into major and minor symptoms and whether complications such as asymptomatic post-biopsy intrahepatic haematoma should be included in the figures. A morbidity rate of 5.9% for patients suffering minor complications after liver biopsy has been reported.[6]

Pain is probably the commonest complication of liver biopsy occurring in up to 30%[3 18] with moderate and severe pain occurring in 3 and 1.5%, respectively.[6] Hypotension and vasovagal episodes are common accompaniments to pain, occurring in about 3% of liver biopsies,[6] and vasovagal episodes occasionally require the administration of atropine.

Significant haemorrhage (indicated by a drop in haemoglobin of >20 g/l) occurs in 0.35–0.5% of all procedures.[16 19] Subclinical bleeding, however, occurs in a much higher percentage of patients, with up to 23% of patients having intrahepatic or subcapsular haematomas detectable by ultrasound 24 hours after biopsy.[20] These haematomas are generally small and are not associated with significant haemodynamic compromise. Haemobilia occurs in 0.05% of patients and patients present with biliary pain, jaundice and melaena; arterial embolisation may rarely be required.

Puncture of other viscera occurs infrequently, with an incidence of between 0.01 and 0.1%.[14] The puncture of lung, colon, kidney and gall bladder together with pneumothorax, pleural effusion, and subcutaneous emphysema are well recognised complications, which rarely require intervention.[21]

Other recognised complications include sepsis, reaction to the anaesthetic, breakage of the biopsy needle,[22] and intrahepatic arteriovenous fistulae.[23]

For other approaches, Riley and colleagues[7] reported one case of a fatal haemorrhage after a plugged liver biopsy in a series of 20 patients. Lebrec and colleagues,[15] in an analysis of 1000 transvenous liver biopsies, reported one death resulting from perforation of the liver capsule, and perforation of the liver capsule in five, haematoma at the site of cannulation in 10, pneumothorax in two, transient supraventricular tachycardia in six, and abdominal pain in 74 patients.

5.0 Indications for liver biopsy

Percutaneous liver biopsy has a small but inherent risk even in the most experienced hands, and it should therefore only be performed when the benefits of knowing the histology outweigh the risks to the patient (in terms of altering treatment or defining disease outcome). These benefits should be continually re-evaluated as new treatment options become available such as has occurred with the new antiviral therapies in viral hepatitis and in liver transplantation.

Acute hepatitis of unknown aetiology, including possible drug related hepatitis, has long been an indication for percutaneous liver biopsy, but liver biopsy in typical acute viral hepatitis is usually not necessary. The usefulness of liver biopsy in chronic viral hepatitis was once hotly debated; however, with the advent of new antiviral therapies there is no doubt of the value of histology in assessing those patients who will benefit from treatment and assessing their response to it.

Patients with chronic hepatitis C virus infection as determined by a positive serum polymerase chain reaction test, who are being considered for antiviral therapy should undergo liver biopsy. Liver biopsy should probably be undertaken even if the patient has normal aminotransferases as it has been reported that up to 50% of patients with active disease have a normal serum alanine aminotransferase.[24] A liver biopsy sample is useful in this instance in allowing an assessment of the Hepatitis Activity Index (a necroinflammatory/fibrosis scoring system[25]) and to identify confounding factors such as alcoholic liver disease and haemochromatosis. Unfortunately, histology of a single liver biopsy sample and the monitoring of aminotransferases are poor predictors of disease progression. Consequently, repeat samples taken every two or three years may be needed to assess disease progression and prognosis.

In patients with raised serum ferritin or where disorders of copper metabolism are suspected, liver biopsy provides material for measurement of iron and copper within the liver parenchyma, although genetic analysis may help to differentiate genetic haemochromatosis from other causes of iron overload. Culture of biopsy material can help in the diagnosis of infections such as tuberculosis.

The need for liver biopsy in patients with intrahepatic cholestasis from primary biliary cirrhosis (PBC) and primary sclerosing cholangitis (PSC) is more controversial. On the one hand, the discovery that a persistently

raised E_2-antimitochondrial antibody (AMA) confirms a diagnosis of PBC (even if patients have no other signs or symptoms of PBC) means that a liver biopsy in the early stages of typical PBC (i.e., a middle aged woman with cholestasis) may be unnecessary.[26] On the other, for more advanced disease liver biopsy may be useful in accurately staging the disease. The diagnosis of PSC related cholestasis is usually made at endoscopic retrograde cholangiopancreatography (ERCP) or MRI cholangiography, and diagnostic histological features in needle biopsy specimens are often not seen.

Liver biopsy is often useful in the diagnosis and management of patients with alcohol related liver diseases, as well as helping in the diagnosis of infections such as tuberculosis. Liver biopsy still remains part of the investigation of pyrexia of unknown origin and is also useful in the diagnosis of storage disorders.

Liver biopsy is often used in the investigation of abnormal liver enzymes but this must be taken in context, tempered by the results of other routine investigations, and take into account the patient's details. For example, the investigation of an isolated raised alkaline phosphatase will be very different in an 80 year old compared with a 25 year old. Raised γ-glutamyl transpeptidase (GGT) activities have been shown to be a sensitive marker of alcohol misuse; however, an isolated increase in GGT is not associated with major liver pathology and is therefore not an adequate indication on its own for liver biopsy.[27]

The role of percutaneous liver biopsy in the diagnosis of focal liver lesions depends largely upon the clinical picture. In most patients with malignant hepatocellular carcinoma ultrasound scanning, CT, and measurement of serum α-fetoprotein will allow a diagnosis to be made (in the context of a space-occupying lesion in a cirrhotic patient). Similarly, a patient with a history of colonic resection for neoplasia who presents with a solitary lesion in the liver associated with raised serum carcinoembryonic antigen, may not require a biopsy of the lesion to make the diagnosis of a potentially resectable metastasis. Liver biopsy also carries a documented risk of seeding tumours down the biopsy track.[28] The magnitude of this risk is currently unknown. Modern imaging techniques can also help to define other types of focal hepatic lesions such as haemangiomata and focal nodular hyperplasia. In these situations, some experts believe that the risk of bleeding after biopsy of a malignant tumour is greatest when the tumour is superficial and so recommend traversing normal liver before sampling tumour tissue. Fine needle aspiration biopsy may be a safer option if material for histological examination is required in the case of a suspected angioma.[29]

The use of liver biopsy after liver transplantation is increasing, and policies on histological monitoring vary between liver transplant units. Some units perform routine biopsies on day 7 after transplant to assess acute rejection, whereas others do annual review biopsies at which abnormalities are frequently seen.[30] Liver biopsy is also useful in the diagnosis of invasive cytomegalovirus infection and in assessing recurrent disease.[31 32]

Using liver biopsy in the context of research is controversial but has undoubtedly given invaluable information in the past in such areas as hepatitis C disease progression and the development of new drugs. We feel that these biopsies should be performed in the context of a clinical trial and where approval has been given by the local research ethics committee. In circumstances where the patient will derive no potential benefit from the procedure, and will thus only accrue the risks of that procedure, the patient should be fully aware of this and give written consent.

6.0 Contraindications

Many of the contraindications to percutaneous liver biopsy were defined by studies performed during the early years when liver biopsy was far less widely used than it is now. These studies were done before the advent of the Menghini "one second" technique and with larger diameter needles and although some of these contraindications seem to be common sense, many of them have been quoted as dogma in medical texts with very little evidence to support them.

6.1 THE UNCOOPERATIVE PATIENT

In percutaneous liver biopsy it is essential that the patient is cooperative as an untoward movement when the biopsy needle is in the hepatic parenchyma can lead to a tear of the liver and capsule and subsequent torrential bleeding. If the patient is frightened, then the use of midazolam as sedation can be considered with no increased risk.[33] If the patient remains uncooperative and the benefit of obtaining liver histology outweighs the risk to the patient, then liver biopsy under general anaesthesia should be considered.

6.2 EXTRAHEPATIC BILIARY OBSTRUCTION

Extrahepatic biliary obstruction is frequently quoted as a contraindication to liver biopsy which may be complicated by pain, biliary peritonitis, septicaemic shock, and death.[34] However, in one study, serious complications in at least 2% of patients (including biliary peritonitis) and significant complications in another 4% followed the percutaneous liver biopsy.[35] With current imaging techniques (specifically ERCP and MRI cholangiography), liver biopsies should only be performed in the context of biliary obstruction when there is doubt about the diagnosis and the benefit to the patient outweighs the risk. Under these circumstances the transjugular approach would be preferable.[36]

6.3 BACTERIAL CHOLANGITIS

The risk of inducing peritonitis and septic shock after liver biopsy has made cholangitis a relative contraindication. However, if a liver biopsy is performed when the biliary system is infected, then culture of a piece of liver can give useful bacteriological information especially in the context of investigation of tuberculosis or a pyrexia of unknown origin. Bacteraemia after

percutaneous biopsy of a normal liver is a well recognised phenomenon[37] and occurs in up to 14% of biopsies.[38] These findings confirm the risks of disseminating infection at the time of liver biopsy.

6.4 ABNORMAL COAGULATION INDEXES

There are widely divergent opinions about the values at which abnormal coagulation indexes become contraindications to percutaneous liver biopsy. A number of investigators have shown that the degree of bleeding from the liver puncture site (observed at laparoscopy) bears no correlation to peripheral blood coagulation parameters, mentioned later, when these parameters are modestly increased.[39 40] Some of these investigators have postulated that this discrepancy in liver bleeding time may be due to the inherent elasticity of the biopsy track collapsing down after the core has been taken, together with the high local concentrations of clotting factors within the hepatic parenchyma.[17] It should, however, be borne in mind that during a blind percutaneous liver biopsy, the liver is not the only structure to be punctured and the skin and subcutaneous tissues (and occasionally other organs) can bleed. Thus, peripheral indexes of clotting must still be taken into consideration.

Liver biopsy may be helpful in determining the extent of liver damage in patients with haemophilia and the benefits of treatment in those infected with hepatitis C virus. In the absence of factor concentrate inhibitors, liver biopsy is safe if the clotting abnormalities are corrected before and for 24 hours after biopsy.[41 42]

6.4.1 *Prothrombin time*

Several large studies have failed to show an increased risk of bleeding associated with a prolongation of the prothrombin time of four seconds above control values.[16 17 39] The largest retrospective study of percutaneous liver biopsy to date failed to show any correlation between a prolongation of prothrombin time by seven seconds over control values and the occurrence of haemorrhagic complications.[14] By contrast, a number of other studies, however, have corroborated the widely held belief that a coagulopathy predisposes the patient to haemorrhage after percutaneous liver biopsy.[43] The 1991 BSG audit of the biopsy practice in 189 health districts in the United Kingdom showed that bleeding was commoner if the international normalised ration (INR) was raised, with 3.3% of the bleeds occurring when the INR was between 1.3 and 1.5, and 7.1% occurring when the INR was >1.5.[3] This suggests that about 90% of the bleeds occurred in patients with an INR<1.3 and reinforces the fact that having a normal INR or prothrombin time is no reassurance that the patient will not bleed after the procedure.

6.4.2 *Thrombocytopaenia*

The level at which thrombocytopaenia becomes a contraindication to percutaneous liver biopsy is uncertain from published data. One authority[44] proposes a platelet count above 100 000/mm^3, whereas other groups such as the Mayo Clinic regard counts as low as 56 000/mm^3 to be safe.[16] Most recognised UK texts require that the platelet count be above 80 000/mm^3,[2] whereas a survey of mostly US centres showed a preference for platelet counts above 50 000/mm^3.[11] One study of 87 patients found that those patients with a platelet count below 60 000/mm^3 were significantly more likely to bleed after percutaneous liver biopsy than those with platelet counts above this value.[45] The evidence for a cut off value remains scanty and takes no account of the function of the platelets (see section 6.4.3).

The effect on bleeding of thrombocytopaenia due to hypersplenism compared with thrombocytopaenia resulting from bone marrow failure has, to our knowledge, not been studied in detail.

The absolute value of the platelet count may not be crucial in determining the risk of bleeding as it is well recognised that even those patients with normal prothrombin times and platelet counts can have severely deranged bleeding times. Nevertheless, for a percutaneous liver biopsy the minimum platelet count felt to be safe without the need for support is 60 000/mm^3.

6.4.3 *Platelet function/bleeding time*

The practice of measuring bleeding time (BT) before liver biopsy is much more common in Asia compared with the USA (73 *v* 36%).[11] Our experience suggests that BT is seldom if ever measured in UK centres prior to liver biopsy even though the ingestion of aspirin and other non-steroidal anti-inflammatory drugs in the week prior to invasive intervention is a recognised contraindication by several authorities. There are to our knowledge, however, no convincing data to support this as a contraindication to percutaneous liver biopsy.

Patients with renal impairment usually have abnormalities of platelet function. According to one small study, patients with end stage renal failure on haemodialysis are at high risk (up to 50%) of haemorrhagic complications after percutaneous liver biopsy, independent of the BT.[46] This same study suggested that liver transplant recipients with a BT above 10 minutes (upper limit of normal) had a higher incidence of bleeding complications compared with those with a BT below 10 minutes. The sample size, however, is too small to allow any firm conclusions to be drawn.

Several other factors are likely to affect platelet function with or without affecting the BT. This fact, together with the considerable variation in results obtained between different operators, makes the use of BT as a measure of risk for haemorrhage difficult to interpret. The Royal Free Hospital was able to show that within a group of cirrhotic patients, those with abnormal BTs (42%) were more likely to have significantly lower platelet counts, longer prothrombin times and higher blood urea and serum bilirubin than those with normal BTs (58%). They also demonstrated that the bilirubin concentration as well as the platelet count were independently correlated with the

BT (although the correlation for the latter was weak, and the raised serum bilirubin may well be just a surrogate marker for the severity of liver disease).[47]

6.5 ASCITES

Percutaneous biopsy of the liver in the presence of tense ascites is considered a contraindication in many texts. The reasons for this vary from the high likelihood of not obtaining a biopsy specimen because of the distance between the abdominal wall and the liver to the risk of uncontrollable bleeding into the ascites. Although these reasons seem to be sensible, they are not substantiated in randomised, controlled clinical trials. There is evidence, however, to support the fact that CT or ultrasound guided liver biopsy in the presence of ascites does not affect the complication rate.[48 49]

Notwithstanding these studies, it seems logical that if a liver biopsy is clinically indicated in a patient with tense ascites then there are several alternatives, the most obvious being to perform a total paracentesis prior to performing the percutaneous biopsy. Other options include image guided biopsy, transjugular liver biopsy, or laparoscopic biopsy.

6.6 CYSTIC LESIONS

Modern imaging techniques can often identify benign cystic lesions of the liver, thereby eliminating the need for biopsy in many cases. Cystic lesions within the liver may communicate with several structures including the biliary tree and therefore pose a risk of biliary peritonitis after biopsy.

The cystic lesion quoted most often as a contraindication to percutaneous liver biopsy was the echinococcal cyst because of the risk of dissemination of the hydatid cysts throughout the abdomen, and the risk of anaphylaxis. Recent advances in the treatment of hydatid disease of the liver mean that this may no longer be so.[50] Aspiration of hydatid cysts with 19–22 gauge needles under ultrasound guidance has been shown to be safe and can be used both diagnostically[51] and therapeutically[52] for the injection of hypertonic saline or 95% ethanol under albendazole cover.

6.7 AMYLOIDOSIS

The use of liver biopsy in the diagnosis of amyloid liver disease was first used in 1928. Volwiler and Jones reported the first death from haemorrhage after amyloid liver biopsy.[53] This episode together with further reports of haemorrhage after liver biopsy in patients with amyloid have lead to the inclusion of amyloid liver disease in the list of contraindications to percutaneous liver biopsy.[53] No large controlled trials have been performed to date which show an increased risk of haemorrhage after liver biopsy in amyloid liver disease. However, in 1961 a small series of liver biopsies in amyloid liver disease was reported. One of 18 patients had an intraperitoneal bleed but this patient was treated conservatively.[54] Stauffer and colleagues[54] decided that liver biopsy was a useful method in the establishment of the diagnosis of hepatic amyloid, and certainly in the context of the investigation of hepatomegaly of uncertain aetiology this seems reasonable. However, if a diagnosis of amyloidosis had already been made or is strongly suspected, then a specific indication for performing a percutaneous liver biopsy is needed rather than for performing a more benign procedure such as a rectal biopsy.

7.0 The biopsy procedure

7.1 INFORMED CONSENT

Informed consent should be obtained in writing prior to the biopsy procedure in accordance with individual hospital policies. Consent forms should contain the patient's native language wherever possible, and when this is not possible there should be access to a competent interpreter to ensure adequate understanding by the patient of both the risks and benefits of the procedure and the commands given to them during the biopsy.

7.2 EXPERIENCE OF THE OPERATOR

There are no good data to show that the grade of the person performing the percutaneous liver biopsy has any affect upon the complication rate after the biopsy. The only data available are that from the 1991 BSG audit showing that the frequency of complications was slightly higher if the operator had performed less than 20 biopsies (frequency of complications was 3.2% if operator had performed <20 biopsies compared with 1.1% if the operator had performed >100 biopsies). No difference in the complication rates between gastroenterologists and general physicians was seen.[3] A radiologist or clinician who is experienced in venous cannulation usually performs transjugular biopsies.

We recommend that pre-registration house officers should not perform percutaneous liver biopsies except in the context of specialised units, and then only under close supervision.

7.3 SEDATION

Anxious patients should be given the opportunity to have midazolam sedation for the biopsy procedure. Sedation should be given in accordance with the BSG guidelines on the administration of sedation for endoscopy. Midazolam should be given with caution in the context of liver disease.

7.4 HAEMATOLOGICAL INVESTIGATIONS

All patients undergoing percutaneous liver biopsy should have blood grouped and serum saved, and in hospitals where facilities for cross matching are limited, patients should have blood available.

The prothrombin time (or INR) and platelet count should be checked prior to the biopsy (preferably within 24 hours). With the current data it can be seen that there is no clear consensus as to the length of the prothrombin time at which the biopsy should not be performed. Consequently we feel that current advice should be followed and thus if the prothrombin time is prolonged by four seconds or more (or INR>1.4) then other strategies to

improve the coagulopathy should be tried (see section 7.4.1).

The level of the platelet count at which a percutaneous liver biopsy should not be done is as controversial (see section 6.4.2); however, there is evidence that in patients with a platelet count as low as 60 000 /mm^3, a percutaneous liver biopsy can be performed with no increase in complication rate.

7.4.1 *Vitamin K, fresh frozen plasma and platelet transfusion.*

Vitamin K, fresh frozen plasma (FFP) and platelet support are widely used for the correction of coagulation abnormalities prior to liver biopsy. There are, however, few data about the values at which correction of these coagulopathies should be abandoned in favour of plugged or transjugular biopsy. Vitamin K is useful but should be given parenterally and at least six hours before the biopsy, and is most effective where the disturbance in coagulation is caused by biliary obstruction or malabsorption. If this does not work then FFP given immediately prior to the biopsy in a dose of 12–15 ml/kg body weight may correct the prothrombin time.[55 56] One study, however, has shown that FFP corrects the prothrombin time in only 20% of cases.[57] Platelet transfusion prior to percutaneous liver biopsy in thrombocytopaenic patients has been used widely but has been hampered by the lack of studies showing its efficacy, especially in the context of patients with liver disease who may have other associated disorders of coagulation. It has been suggested that patients should initially receive 1 unit per 10 kg body weight and the effect of this transfusion be assessed by the platelet count obtained one hour later.[58] However, post-transfusion platelet increments do not necessarily correlate with decreased risk of bleeding as platelet function may vary and it has been shown that 30% of patients receiving platelet transfusion show no improvement in in vitro bleeding time (a measure of platelet function).[59]

7.5 PRE-BIOPSY ULTRASOUND

Whether all patients about to undergo percutaneous liver biopsy should have an ultrasound is a contentious issue. Ultrasound is a safe and readily available investigation. Mainland European gastroenterologists are already required to be proficient in this method of imaging and it seems probable that before long all UK gastroenterologists will be trained to perform ultrasound at the bedside before or during the biopsy procedure. However, this is not current practice in the United Kingdom.

One of the reasons for performing a pre-biopsy ultrasound is to rule out anatomical variation—for example, Chilaiditi syndrome where bowel lies between the liver and the abdominal wall, thereby avoiding inadvertent puncture of an adjacent viscus.[60] Ultrasound also permits the detection of focal lesions (which may or may not have been suspected) allowing for the opportunity of a targeted biopsy or fine needle aspiration at a later date under image guidance with a lower risk of haemorrhage.

Percussing for the superior and inferior borders of the liver is usually adequate for selection of the biopsy site[61]; however, in some patients where the borders of the liver are unclear (e.g. obese or cirrhotic patients) ultrasound is helpful.

7.6 ULTRASOUND GUIDED PERCUTANEOUS LIVER BIOPSY

Ultrasound guided percutaneous liver biopsy is used extensively in the investigation of focal liver lesions; however, its use in diffuse liver disease is more controversial. It has been postulated that ultrasound guided biopsy should reduce complications. As the commonest cause of mortality is bleeding, it follows that the incidence of bleeding should be proportional to the incidence of haematoma formation. The rate of haematoma formation however is unaffected by the use of ultrasound guidance.[62] It is also difficult to understand why ultrasound should prevent haemorrhage (which is usually due to the rupture of large hepatic blood vessels) unless as postulated by Stotland and Lichtenstein, it leads to a reduction in the number of passes made into the liver.[21] This may be especially important in the context of a shrunken liver where ultrasound may be used to perform the procedure accurately the first time. The increased risk of bleeding associated with multiple biopsy passes has been documented in patients with and without malignancy[16] and has lead to the suggestion that all hepatic tumours should be biopsied by ultrasound or CT guided fine needle aspiration.

There is only one large series in which the use of ultrasound has been assessed in the context of diffuse liver disease. This paper was criticised for a number of reasons including the fact that it was retrospective and therefore subject to recall bias, that the sample size (although the largest study so far) was relatively small, and that the number of passes used in the control group was not documented (see section 8.8).[21] This same paper quotes a significant reduction in major complications; however, there were no deaths and only one patient required therapeutic intervention in the form of a transfusion.[63] These findings are consistent with a previous large retrospective study of 68 276 biopsies, which concluded that complications of liver biopsy such as pneumothorax and puncture of other viscera seldom require intervention.[14]

The use of ultrasound examination to assist in liver biopsy for non-focal disease has been estimated to be cost effective in the United States if the additional cost of ultrasound is less than US$102 (£64).[64]

We believe that the use of guided liver biopsy or fine needle aspiration in the diagnosis of hepatic tumours is the safest way of managing these patients. It is also useful to have a pre-biopsy ultrasound to rule out any anatomical abnormalities and in patients in whom the liver cannot be easily identified for reasons such as obesity.

7.7 PROPHYLACTIC ANTIBIOTICS

Bacteraemia associated with liver biopsy in both structurally normal and abnormal livers has been well documented.[37 38] Therefore, prophylactic antibiotics should be used in the context of valvular heart disease or when there is previously documented bacteraemia.

Several groups have assessed the risks of septic complications for patients with choledochojejunostomy after liver transplantation. The conclusions of the Mayo group were that there was an increased risk (12.5%) of septic complications in these patients,[65] whereas the Royal Free group could show no increased risk providing there was no occult biliary obstruction.[66] The latter study had too few patients to be able to make strong recommendations; however, other groups have come to the same conclusions.[67]

The current data on the use of prophylactic antibiotics are inconclusive and we feel that for patients in whom biliary sepsis is suspected it is prudent to use antibiotics.

7.8 TYPE OF BIOPSY NEEDLE

The two main types of needle currently being used in the United Kingdom are the Tru-cut and the Menghini needles.[3] These two needles use different methods for sampling hepatic tissue. The former, as its name describes, is a cutting needle, whereas the latter uses a suction technique. These needles come in varying diameters, and the type and gauge of needle that is optimal for percutaneous liver biopsy have been the subject of several studies.

The largest series to look at needle type in relation to complications describes a complication rate of 3.5/1000 for the Tru-cut needle and 1/1000 for the Menghini needle. Death, serious haemorrhagic complications, pneumothorax, and biliary peritonitis all occurred more frequently with the Tru-cut needle than with the Menghini needle, whereas puncture of other viscera and sepsis were more frequent with the Menghini needle.[14] Other groups have compared the older Jamshidi suction needle with the Tru-cut/Vim Silverman cutting needles and found no difference in complication rates.[6 16] The theoretical advantages of the Menghini suction technique were described in the original paper,[68] the main advantage being that the needle is only in the liver parenchyma for a "second". This allows less time for the patient to move, thereby minimising the potential for tearing the capsule.

The gauge of the biopsy needle and its effect on post-biopsy bleeding has been investigated for the suction style needle. One group showed that larger needles produced more bleeding after liver biopsy in anaesthetised pigs. This was statistically significant when comparing 2.1 mm (14 gauge) with 1.6 mm (16 gauge) needles, and also when comparing 1.6 mm with 1.2 mm (18 gauge) and smaller needles.[40] Human studies of the effect of biopsy needle diameter on complications are rare; however, Forssell and colleagues[18] could not show any difference in the incidence of intrahepatic haematoma formation when they compared the 1.6 mm modified Menghini needle with a 1.9 mm Jamshidi needle.

The potential advantages of using smaller suction biopsy needles should be weighed against the disadvantages of having a smaller biopsy specimen. Specimens from the Tru-cut needles are larger and give more information about liver architecture and may thereby increase the diagnostic yield. The disadvantages of making several passes of the biopsy needle should also be borne in mind (see later).

7.9 NUMBER OF PASSES

It has been demonstrated that taking more than one core of liver at biopsy can increase the diagnostic yield, but this may have an effect on morbidity. It has been clearly shown that making more passes increases the incidence of complications when the percutaneous biopsy is taken by either transthoracic or subcostal approaches. In one paper the increased incidence reached significance when more than three biopsy samples were taken.[6] This was subsequently confirmed by other studies showing that when blind percutaneous liver biopsy is undertaken, taking two specimens improves diagnostic yield with an increased number of minor complications when more than three consecutive specimens are taken.[69]

A large study of 9212 liver biopsies also showed that the risk of haemorrhage does not only increase with the number of passes made, but is also significantly linked to the age of the patient and the presence of malignancy.[16] Therefore we conclude that under circumstances where the likelihood of a sampling error is high, such as in some cases of macronodular cirrhosis, two samples could be taken. However, the decision to do this for patients with advanced age or malignancy should be tempered by the increased risk of complications.

7.10 POST-BIOPSY OBSERVATION

The decision about the length of time that a patient should remain in hospital after a blind percutaneous liver biopsy is dependent on several factors. The main consideration in practical terms however is the likely time period in which complications are going to occur.

It has been shown that delayed haemorrhage can occur up to 15 days after percutaneous liver biopsy in patients who develop a post-biopsy coagulopathy.[70] The occurrence of delayed haemorrhage is also documented after the reinstatement of warfarin therapy several days after percutaneous liver biopsy. Clearly, patients cannot be kept in hospital for two weeks or more after liver biopsy so a compromise has to be made on the basis of current knowledge.

The first large studies addressing the issue of post-biopsy observation were stimulated by the drive to perform outpatient percutaneous liver biopsies. These papers showed that the majority of complications occurred in the first three hours after liver biopsy,[6 19] and recommended that patients should be kept in hospital for six hours after the procedure. A later paper described 61% of complications after liver

biopsy occurring in the first two hours, 82% of complications occurring in the first 10 hours, and 96% of complications occurring in the first 24 hours. In this paper recounting 68 276 liver biopsies, six patients died, and all showed signs of bleeding within six hours of the procedure.[14]

The position that the patient should be nursed in after the liver biopsy has not been investigated, and various centres have differing policies including nursing the patient supine, on their right hand side or simply "flat".[6 71] No controlled trials have been performed to assess these different techniques. Standard percutaneous liver biopsy observations include monitoring the patient's vital signs every 15 minutes for the first two hours, then every 30 minutes for two hours and then hourly for the rest of the remaining period. This protocol is reasonable when one considers that 61% of complications occur within the first two hours.

8.0 Outpatient percutaneous liver biopsy

Outpatient percutaneous liver biopsy has been performed in many US centres since the early 1970s.[6] In 1991 this practice had not been widely taken up in the United Kingdom with only 4% of percutaneous liver biopsies being performed as day cases.[3] In centres which do perform day case biopsies in this country a 91% patient satisfaction rate has been quoted, and in carefully selected populations the admission rate to hospital after day case liver biopsy is 2.2–3.2%.[71 72]

In 1989 the American Gastroenterological Association published a consensus statement on outpatient percutaneous liver biopsy which we feel largely applies to UK patients.[73] They recommended that patients undergoing this procedure should have no conditions that might increase the risk of the biopsy including: encephalopathy, ascites, hepatic failure with severe jaundice or evidence of significant extrahepatic biliary obstruction, significant coagulopathies or serious diseases involving other organs such as severe congestive heart failure or advanced age. We would add that patients with a strong suspicion of malignancy should not be biopsied as an outpatient because they have a 6–10 times higher risk of haemorrhage compared with patients without cancer.[16]

The consensus statement also recommends that the place where the biopsy is performed should have easy access to a laboratory, blood bank and inpatient facilities should the need arise, and there should be staff to observe the patients for six hours. The patient should be admitted to hospital if there is any significant complication including pain requiring more than one dose of analgesic in the four hours after liver biopsy. The patient should also be able to return easily to the hospital where the biopsy was undertaken within 30 minutes, and should have a reliable individual to stay with on the first post-biopsy night.

If the above criteria cannot be met, then the patient should not be biopsied as an outpatient.

Performing percutaneous liver biopsies as an outpatient has considerable potential for cost saving and reallocation of resources.[6]

9 Recommendations

- Before performing a percutaneous liver biopsy, there must be a clearly defined indication for the biopsy, and the risks to the patient should not outweigh the potential benefits.
- We recommend that all patients who are about to undergo a percutaneous liver biopsy should have had some form of imaging of the liver within the preceding four weeks. This will allow the detection of abnormal anatomy in the area of the proposed biopsy (see section 7.5), while at the same time detecting focal lesions which should be biopsied under image guidance. *Recommendation grade B*.
- The patient's platelet count and prothrombin time should be checked in the week before the percutaneous liver biopsy providing that the patient's liver disease is stable.
  - If the platelet count is > 60 000/mm^3 then the biopsy can be safely performed. If the platelet count is 40 000–60 000/mm^3 then platelet transfusion may increase the count enough for the biopsy to be performed safely by the percutaneous route. If, however, platelet transfusion does not increase or the platelet count is <40 000/mm^3 then alternative biopsy methods such as plugged, transvenous (transjugular), or laparoscopic liver biopsy can be tried (see sections 6.4 and 7.3). *Recommendation grade B*.
  - If the prothrombin time is <4 seconds prolonged, then percutaneous biopsy can be safely undertaken. If the prothrombin time is 4–6 seconds prolonged then, a transfusion of fresh frozen plasma may bring the prothrombin time into the desired range (see sections 6.4 and 7.4). If the prothrombin time is >6 seconds prolonged then other biopsy methods should be tried. *Recommendation grade B*.
- Informed consent should be obtained from all patients prior to percutaneous liver biopsy in accordance with local hospital guidelines. The patient should also be able to understand and cooperate with instructions given by the person performing the liver biopsy (see section 7.1).
- Sedation with midazolam may be given for percutaneous liver biopsy in accordance with the BSG guidelines on sedation during endoscopy. Sedation should be given with caution in liver disease (see section 6.1). *Recommendation grade B*.
- The type of needle used for the biopsy will depend on the experience of the operator and the type of needle they are used to. Where a larger biopsy is not required the Menghini needle should be used in preference to cutting needles as this technique seems to have a lower complication rate (which may however be at the expense of the diagnostic yield). Where the operator has only experience of one style of needle they should use the technique most familiar to them (see section 7.8). *Recommendation grade A*.

- The grade of the operator has not been shown adversely to affect the complication rate from percutaneous liver biopsy. We feel, however, that doctors who have performed less than 20 biopsies should not perform the procedure unsupervised and that house officers should not be performing percutaneous liver biopsies except in the context of a busy specialised gastrointestinal unit (see section 7.2). *Recommendation grade B*.
- Prophylactic antibiotics should be given to patients with valvular heart disease or those at risk of bacteraemia (section 7.7). *Recommendation grade B*.
- Usually one pass of the biopsy needle retrieves enough hepatic tissue for diagnostic purposes; however, if there may be a sampling error (such as may occur in macronodular cirrhosis) which will result in an inappropriate diagnosis, then two passes may be made without significantly affecting the complication rate (see section 7.9.). *Recommendation grade B*.
- We recommend that patients undergoing outpatient percutaneous biopsy should not have any condition that may increase the risk of the biopsy procedure (see section 8). *Recommendation grade B*.
- Post liver biopsy observation should continue for six hours and if at the end of this period there have been no complications then the patient may be discharged. The patient should, however, have a responsible person to stay with on the first post-biopsy night and should be able to return to hospital within 30 minutes should the need arise (see section 7.10). *Recommendation grade B*.

Dr A J Grant and Professor J Neuberger, University Hospital, Birmingham, UK, have formulated these guidelines. Within the boundaries of current literature we have attempted where possible to make the guidelines evidence-based.

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CLINICAL GUIDELINES

Guidelines for Care of a Patient Undergoing a Liver Biopsy	
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This guideline has been registered with the Trust. However, clinical guidelines are guidelines only. The interpretation and application of clinical guidelines will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using the guidelines after the review date.	

Nottingham University Hospitals NHS Trust

CLINICAL GUIDELINES

CARE OF A PATIENT UNDERGOING A LIVER BIOPSY

INTRODUCTION

A liver biopsy is the removal of a small piece of liver tissue for histological examination. This can be done in the following three ways: (BSG guidelines 2004)

a. percutaneous
b. ultrasound scan guided
c. transjugular

Transjugular Method

A transjugular liver biopsy is performed by inserting a special Trucut needle through a catheter placed in the hepatic vein, via the jugular vein, into the liver to obtain a tissue sample. This method is preferred for patients with abnormal clotting times and patients who may have ascites. Another advantage is that pressure in the liver veins (to assess the presence of "portal hypertension") can also be measured at the same time (BSG guidelines 2004). The patient is sedated. It is performed by radiologists after obtaining written, informed consent.

ANATOMY AND FUNCTION

The liver is the largest organ in the body, weighing an average of 1.5kg (3lbs). It is situated below the diaphragm in the right upper abdomen.

The liver is highly vascular and receives its blood supply from the hepatic artery and the hepatic portal vein from the intestines and spleen (Marieb,2010).

The liver's functions are many and complex and include:

- Metabolism of nutrients;
- Breakdown of erythrocytes;
- Formation of bile;
- Inactivation of hormones;
- Storage of vitamins;
- Formation of clotting factors;
- Regulation of body temperatures (Sherlock, 2007).

INDICATIONS AND CONTRAINDICATIONS

Indications for liver Biopsy

- Investigation of suspected liver disease;
- Unexplained hepatomegaly;
- Persistently abnormal liver biochemistry
- Assess the degree of fibrosis (scarring) or cirrhosis;
- Drug-induced liver disease ("DILI");
- Tumour biopsy (primary or metastatic)
- Assessing liver damage in inheritable conditions (e.g. haemochromatosis);
- Pyrexia of unknown origin/ assessment for tuberculosis.

Usual Contraindications to percutaneous liver biopsy:

- Uncooperative patient;
- *Prolonged prothrombin time (> 4 seconds) (BSG guidelines 2004);
- *Platelets < 60 x 10^9/litre (Grant et al, 2004);
- *Ascites
- Extrahepatic cholestasis. (Kumar & Clark, 2009)

* transjugular biopsy can be perfomed in these circumstances

HAZARDS

Due to its highly vascular structure, a biopsy of the liver carries a risk of haemorrhage during and after the procedure (Marieb 2010). Patients should be advised to stop antiplatelet agents and anticoagulants like asprin and warfarin 7 days before the procedure. It is strongly advised that a full patient drug history is obtained and that the patient has the following investigations prior to the procedure (Long & Scott,2005):

a. a full blood count (measures platelets) and clotting (measures prothrombin time). If the transjugular route is chosen, then a group and save is also required.

   These blood tests are usually performed prior to the procedure to minimise both the risk and delay to the patient. However, the clotting test is performed on the day or the day prior to the procedure to obtain the most accurate and up-to-date result.

   If the PT≥4 s or platelets≤60 medical staff may plan to transfuse patient with FFP or platelets during the procedure or before the procedure. If it is done before the procedure a repeat PT/PTT and FBC must be checked to ensure the desired effect has been achieved.

b. an ultrasound of the abdomen to determine the size and position of the liver. The presence of ascites or any significantly abnormal coagulation profile (as described above) would indicate preference for the transjugular route.

The major risk of having a standard liver biopsy is internal bleeding at the site where the needle enters the liver. A small amount of bleeding around the site is expected and usually resolves quickly without treatment. However six in every 1000 people have a serious bleed after having a liver biopsy and most of these require a blood transfusion alone. About one in 2,500 to 3,000 people may also require an operation to stop the bleeding. Puncture of other organs, such as lungs, kidneys, gallbladder and the gut are uncommon (about two in 1000) but if this occurs surgery may be required. For every 10000 biopsies done about 1 person will unfortunately die from the complications of the procedure (West and Card 2010). The risk is higher in those having a biopsy of a liver tumour for diagnosis.

EQUIPMENT LIST

Basic dressing pack
Sterile gauze
Antiseptic agent – e.g. chlorhexadine or Povidone iodine with alcohol
Sterile gloves
Local anaesthetic – lignocaine 2%
10ml syringe
1 orange, 1 blue, 1 green needle and one to draw up lignocaine(Gilmore IT& Burroughs A 1995)

Sterile dressing – allowing any swelling to be visible
Specimen pot containing formalin
Biopsy needle as requested
Size 11 scalpel
Sterile drape
Plaster for skin wound

Ward ultra sound machine (Sonosite)

If IV access is required a cannulation pack needs to be available (see local Trust Guidelines for cannulation (NUH Policy Guidelines 2010)

PRINCIPLES OF CARE

See General Principles for All Procedures.

	PRINCIPLE	RATIONALE
1.	The procedure is routinely performed in the morning. The patient has a light breakfast no later than two hours before the procedure.	This may reduce the risk of nausea and vomiting during the procedure.(Rockey 2009)
2.	Ensure patient fully understands the procedure, obtain and record informed consent and the need for co-operation with the person performing biopsy.	To reduce patient anxiety and improve technical success To ensure that patients who lack capacity can be identified and treated as per Trust Policy on consent (NUH Consent Policy 2010)
3.	The nurse opens the dressing pack onto the trolley maintaining a sterile field. Dispense onto the field sterile gloves ,syringe, needles and cleansing solution and sterile plaster dressing.	To keep potential areas of contamination to a minimum and to ensure correct equipment is readily available. Infection Control Guideline (NUH 2010)
4	Assist the patient into a supine position with his/her right side as close to the edge of the bed as possible with the right hand placed beneath the head and stay with the patient.	To allow access to the liver for the biopsy to be performed and ensure patient safety. (Rockey DC 2009) BSG 2004
5	The doctor cleans the skin	To minimise risk of introducing bacteria into abdominal cavity during the biopsy BSG (2004)
6.	The nurse to check ampoule of lidocaine for content and expiry date with the doctor and open, ensure safe disposal of sharps in sharps bin After the procedure.	To minimise and prevent sharps injury. To maintains patient safety. Nursing and midwifery Council code of conduct 2008 (NUH Sharps disposal policy Guideline) 2010
7	The biopsy is obtained by the doctor • After infiltration of the local anaesthetic • A small incision is made (generally at the 8thor 9th intercoastal space mid-axillary line) . • The needle is inserted a short distance and the biopsy obtained.	To minimise pain during the procedure To facilitate puncture

	• Whilst the patient is holding their breath the needle is with drawn in a single smooth action • The specimen is discharged into the appropriate container • Occasionally a second pass is required. • Apply pressure 3-4 minutes to puncture site • Cover the wound with sterile plaster There is no need to apply a pressure dressing.	To preserve the tissue for examination To provide sufficient tissue To reduce haemorrhage risk Haemorrhage tends to be intra-abdominal. If haemorrhage was external, this may be obscured by a pressure dressing (McGill et al, 1990).
8	The nurse should ensure the correct sterile specimen pot is at hand and is correctly labelled with patient details	To make sure positive identification is maintained (NMC Record Keeping Guidelines 2009: NUH Positive Identification Guidelines) .
9.	If instructed by medical staff, ask the Patient to lie on their right side for the first 1 – 2 hours.	To compress the liver capsule against the chest wall to minimise the risk of haemorrhage (BSG) (Gilmore & Burroughs 1995)
10.	The patient must remain on bed rest for a minimum of 4 hours. If instructed by medical staff, ask the patient to lie on their right side for the first 1 – 2 hours.	To facilitate early detection of haemorrhage To compress the liver capsule against the chest wall to minimise the risk of haemorrhage.

	PRINCIPLE	RATIONALE
11.	Record and report blood pressure and pulse ¼ hourly for 1 hour, ½ hourly for 2 hours then hourly for 2 hours and check dressing for bleeding and swelling ¼ hourly for 1 hour and then hourly.	To detect signs of haemorrhage To detect signs of haemorrhage and patient deterioration using the local observation policy EWS.(NUH Policy Management of acutely ill patient) .
12.	Monitor for and record signs of abdominal pain every time observations are recorded and, if present, report to medical staff.	This may indicate intra-abdominal haemorrhage or leakage of bile into the peritoneum caused by inadvertent puncture of the bile duct. Pain occurs in 30% of patients after biopsy and early administartaion of analgaesia is preferable (BSG 2004).
13.	Observe for dyspnoea and chest pain and, if present, report immediately to medical staff.	This may indicate intra-abdominal haemorrhage or pneumothorax due to puncture of the right lung. The breathing in may cause the pneumothorax as the biopsy needle is introduced.
14.	Ensure written information and advice, including a contact telephone number, is given to all patients on discharge.	To ensure prompt recognition of post-procedure complications by the patient and facilitation of access to specialist advice(NMC 2008/2009).

Best Practice Transjugular Liver Biopsy

It is recommended good practice that patients who fall into a higher risk category after pre-procedure investigations, i.e. presence of ascites, elevated clotting times, be offered biopsy via the transjugular route. This is performed in the X Ray Department by radiologists. Post procedure, the patient will require 4 – 6 hours bed rest and observation of the neck wound for bleeding. This can also be perfomed as a daycase procedure is observations and patient comform scores are satisfactory.

Best Practice Sedation

Medical staff views regarding sedation for patients may vary. However, the rationale for sedation is to facilitate a relaxed, cooperative patient who is less anxious, which is especially important if the biopsy has to be repeated either because it had previously been abandoned or for disease progress checks, e.g. patients with Hepatitis C. (McCloy, 1991; Londrum, 1997).

Equality and Diversity Statement

All patients, employees and members of the public should be treated fairly and with respect, regardless of age, disability, gender, marital status, membership or non-membership of a trade union, race, religion, domestic circumstances, sexual orientation, ethnic or national origin, social & employment status, HIV status, or gender re-assignment.

All trust polices and trust wide procedures must comply with the relevant legislation (non exhaustive list) where applicable:

Equal Pay Act (1970 and amended 1983)
Sex Discrimination Act (1975 amended 1986)
Race Relations (Amendment) Act 2000
Disability Discrimination Act (1995)
Employment Relations Act (1999)
Rehabilitation of Offenders Act (1974)
Human Rights Act (1998)
Trade Union and Labour Relations (Consolidation) Act 1999
Code of Practice on Age Diversity in Employment (1999)
Part Time Workers - Prevention of Less Favourable Treatment Regulations (2000)
Civil Partnership Act 2004
Fixed Term Employees - Prevention of Less Favourable Treatment Regulations (2001)
Employment Equality (Sexual Orientation) Regulations 2003
Employment Equality (Religion or Belief) Regulations 2003
Employment Equality (Age) Regulations 2006
Equality Act (Sexual Orientation) Regulations 2007

Equality Impact Assessment Statement

NUH is committed to ensuring that none of its policies, procedures, services, projects or functions discriminate unlawfully. In order to ensure this commitment all policies, procedures, services, projects or functions will undergo an Equality Impact Assessment.

Reviews of Equality Impact Assessments will be conducted inline with the review of the policy, procedure, service, project or function

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ELEMENTS FOR ASSESSMENT OF CLINICAL COMPETENCE

Knowledge

Anatomy and function of the liver and biliary tract
Pathophysiology and reason for invasive procedure
Normal pre procedure blood values and contraindications

Skills

Selection and preparation of correct equipment and medication
Safe, effective assistance to medical staff throughout the procedure
Accurate observation of patient post procedure

Timely reporting of adverse reactions to medical staff
Ability to perform Positive Patient Identification

Attitudes
Effective communication with patient
Explanations of practice are appropriate

Revised 2013 (Resolution 35)*

ACR–SIR–SPR PRACTICE GUIDELINE FOR THE PERFORMANCE OF IMAGE-GUIDED PERCUTANEOUS NEEDLE BIOPSY (PNB)

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline was revised collaboratively by the American College of Radiology (ACR), the Society of Interventional Radiology (SIR), and the Society for Pediatric Radiology.

Image-guided percutaneous needle biopsy (PNB) is an established, effective procedure for selected patients with suspected pathology. Extensive experience documents its safety and efficacy. The patient is most likely to benefit

when the procedure is performed in an appropriate environment by qualified physicians [1-3]. This guideline outlines the principles for performing PNB.

For information on breast biopsy, see the ACR Practice Guideline for the Performance of Stereotactically Guided Breast Interventional Procedures or the ACR Practice Guideline for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures.

II. DEFINITION

PNB is defined as percutaneous placement of needles into a suspected abnormal lesion or organ for the purpose of obtaining tissue, cells, or fluid for diagnosis. Following specimen procurement, the needles are removed.

For purposes of this guideline, successful image-guided PNB is defined as the procurement of sufficient material to establish a pathologic diagnosis or to guide appropriate patient management. At times nondiagnostic materials may be obtained; at the discretion of the referring clinician and interventional radiologist, repeat biopsy can be considered.

III. INDICATIONS AND CONTRAINDICATIONS

A. Indications for PNB include, but are not limited to:

1. To establish the benign or malignant nature of a lesion.
2. To obtain material for microbiologic analysis in patients with known or suspected infections.
3. To stage patients with known or suspected malignancy when local spread or distant metastasis is suspected.
4. To determine the nature and extent of certain diffuse parenchymal diseases (e.g., hepatic cirrhosis, renal transplant rejection, glomerulonephritis).
5. To obtain tissue for biomarker, protein, or genotype analysis to subsequently guide therapy.
6. To determine the primary cell of origin in a patient with metastatic disease and an unknown primary tumor.

B. There are no absolute contraindications. However, there are relative contraindications and, as for all patients considered for this procedure, the relative risks of the procedure should be weighed carefully. These relative contraindications should be addressed and corrected or controlled before the procedure, when feasible. The relative contraindications for PNB include:

1. Significant coagulopathy that cannot be adequately corrected.
2. Severely compromised cardiopulmonary function or hemodynamic instability.
3. Lack of a safe pathway to the lesion.
4. Inability of the patient to cooperate with, or to be positioned for, the procedure.
5. Patient refusal of biopsy.

For the pregnant or potentially pregnant patient, see the ACR–SPR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Image-based diagnosis and treatment planning require integrating the preprocedural imaging findings within the context of the patient's history and physical findings. Therefore, the physician must be clinically informed and understand the specific questions to be answered and goals to be accomplished by PNB prior to the procedure in order to plan and perform it safely and effectively.

The physician performing PNB must have knowledge of the benefits, alternatives, and risks of the procedure. The physician must have an understanding of imaging anatomy, imaging equipment, radiation safety considerations, and physiologic monitoring equipment, and have access to adequate supplies and personnel to perform the procedure safely and manage potentially related complications.

PNB procedures must be performed by a physician who has the following qualifications. The physician's experience in PNB is best documented by use of a formal case log submitted by the applicant.

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of PNB procedures to demonstrate competency as attested by the supervising physician(s).

   or

2. Completion of a residency program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) and has performed (with supervision) a sufficient number of PNB procedures to demonstrate competency as attested by the supervising physician(s).

   or

3. Physicians whose residency or fellowship training did not include the above may still be considered qualified to perform PNB provided that the following can be demonstrated:

   The physician must have at least 2 years of image-guided procedural experience during which the physician was supervised, and during which the physician performed and interpreted at least 35 image-guided percutaneous biopsy procedures, 25 of them as primary operator, with outcomes within the quality improvement thresholds of this guideline.

   and

4. Physicians meeting any of the qualifications in 1, 2, and 3 above also must have written substantiation that they are familiar with all of the following:
   a. Indications and contraindications for the procedure.
   b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and potential complications.
   c. Where applicable, pharmacology of moderate sedation medications and recognition and treatment of adverse reactions and complications.
   d. Imaging systems that may be used for guidance during percutaneous procedures and determining which imaging modality would be optimal for a specific PNB procedure in terms of both safety and effectiveness.
   e. Where applicable, principles of radiation protection, the hazards of radiation, and radiation monitoring requirements.
   f. Where applicable, pharmacology of contrast agents and recognition and treatment of potential adverse reactions.
   g. Percutaneous needle introduction techniques.
   h. Technical aspects of performing the procedure, including the use of various biopsy devices.
   i. Anatomy, physiology, and pathophysiology of the structures being considered for PNB.

The written substantiation should come from the chief of interventional radiology, the director or chief of body imaging or ultrasound, or the chair of the radiology department of the institution in which the physician will be providing these services. Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the current interventional director or chair who solicits the additional input.

Maintenance of Competence

Physicians must perform a sufficient number of procedures to maintain their skills, with acceptable success and complication rates as laid out in this guideline. Continued competence should depend on participation in a quality improvement program that monitors these rates.

Continuing Medical Education

The physician's continuing medical education should be in accordance with the ACR Practice Guideline on Continuing Medical Education (CME).

B. Qualified Medical Physicist

A Qualified Medical Physicist should have the responsibility for overseeing the equipment quality control program and for monitoring fluoroscopy and other cross-sectional imaging equipment, both upon installation and routinely on an annual basis. Medical physicists assuming these responsibilities should meet the following qualifications:

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or by the American Board of Medical Physics (ABMP).

The Qualified Medical Physicist should meet the ACR Practice Guideline for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised 2012, Resolution 42)

The appropriate subfield of medical physics for this guideline is Diagnostic Medical Physics. (Previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable.)

C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled "Radiologist Assistant: Roles and Responsibilities" [4] and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006)

D. Radiologic Technologist

The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position[1] the patient for the image-guided percutaneous procedure and, together with the nurse, monitor the patient during the procedure. The technologist should provide assistance to the physician as required, which may include operating the imaging equipment and obtaining images prescribed by the supervising physician. If intravenous contrast material is to be administered, qualifications for technologists performing intravenous injection should be in compliance with current ACR policy statements[2] and existing operating procedures or manuals at the facility. The technologist should also perform regular quality control testing of the equipment under supervision of the physicist.

Technologists should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in the imaging modality used for the image-guided percutaneous procedure.

E. Diagnostic Medical Sonographer

The sonographer, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The sonographer should be able to prepare and position the patient for the image-guided percutaneous procedure and, together with the nurse, monitor the patient during the procedure. The sonographer should provide assistance to the physician as required, which may include operating the imaging equipment and obtaining images prescribed by the supervising physician. The sonographer should also perform regular quality control testing of the equipment under supervision of the physicist.

Diagnostic medical sonographers involved in PNB should have documented training and experience in assisting with these procedures. When possible, they should be certified by the ARRT or by the American Registry for Diagnostic Medical Sonography (ARDMS). When applicable, they should have an unrestricted state license.

F. Computed Tomography Technologist

For biopsies performed using computed tomography (CT), the CT technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position the patient for the image-guided percutaneous procedure and, together with the nurse, monitor the patient during the procedure. The CT technologist should provide assistance to the physician as required, which may include operating the imaging equipment and obtaining images prescribed by the supervising physician. The CT technologist should also perform regular quality control testing of the equipment under supervision of the physicist.

CT technologists should be certified by the ARRT or have an unrestricted state license with documented training and experience in CT.

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[1]The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available*. There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (ACR Resolution 26, 1987 – revised in 2007, Resolution 12m)
*For the purposes of this guideline, "personally and immediately available" is defined in manner of the "personal supervision" provision of CMS—a physician must be in attendance in the room during the performance of the procedure. Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001.

[2]See the ACR–SPR Practice Guideline for the Use of Intravascular Contrast Media.

G. Other Ancillary Personnel

Other ancillary personnel who are qualified and duly licensed or certified under applicable state law may, under supervision by a radiologist or other qualified physician, perform specific interventional fluoroscopic or other image-guided procedures. Supervision by a radiologist or other qualified physician must be direct or personal, and must comply with local, state, and federal regulations. Individuals should be credentialed for specific fluoroscopic and other image-guided interventional procedures and should have received formal training in radiation management and/or application of other imaging modalities as appropriate.

H. Nursing Services

Nursing services, when deemed appropriate by the performing physician, are an integral part of the team for preprocedural**,** intraprocedural**,** and postprocedural patient management and education and are recommended in monitoring the patient during the procedure.

I. Nonphysician Practitioner

Physician assistants and nurse practitioners can be valuable members of the interventional radiology team but should not perform PNBs independent of supervision by physicians with training, experience and privileges to perform the relevant procedures. See the ACR–SIR–SNIS Practice Guideline for Interventional Clinical Practice.

V. SPECIFICATIONS AND PERFORMANCE OF THE PROCEDURE

A. Imaging Equipment and Facilities

1. The minimum requirements for facilities in which PNB is performed include:
   a. When fluoroscopic guidance is used, a high-resolution unit with adequate shielding and collimation is desirable. Ability to perform complex angle (e.g., anteroposterior, lateral, or oblique) fluoroscopy views is often necessary to ensure proper needle placement. Overhead fluoroscopic tube suites are less desirable because of increased radiation exposure to personnel during this procedure.
   b. When appropriate, availability of ultrasound is desirable. Proper transducer frequency is required to direct and monitor needle placement.
   c. At times, CT and/or CT fluoroscopy equipment may be necessary to better demonstrate anatomy, particularly in:
      i. Patients with lesions that are difficult to visualize or access with other modalities, or are in unusual or precarious locations.
      ii. Planning the optimal route of biopsy to avoid, when possible, transgression of vital structures.
      iii. Patients with unusual anatomy.
   d. The facility should provide an area within the institution appropriate for patient preparation and for observation after the procedure. This might be within the radiology department, in a short-stay unit, or in a routine nursing unit as outlined in the Patient Care Section below. There should be immediate access to emergency resuscitation equipment. Personnel and equipment to diagnose and treat acute complications should also be available.
   e. For patients undergoing thoracic procedures, appropriate equipment for decompression of a tension pneumothorax should be available.
   f. Access to laboratory facilities with expertise in cytopathology, microbiology, and chemistry should be available. (These resources need not be located in the biopsy facility.)

2. Performance guidelines

   When using fluoroscopy for PNB, a facility should meet or exceed the following imaging practices:
   a. Fluoroscopic times for both X-ray and CT guidance should be kept to a minimum. The operator will use only as much fluoroscopy as is necessary to complete the biopsy, consistent with the as low as

reasonably achievable (ALARA) radiation safety guidelines. One method to minimize fluoroscopic time is to use units with "last image hold" capability [5].

b. Tight collimation and, when appropriate, shielding (e.g., thyroid, gonadal, eye) should be used for the operating radiologist, for the patient, and for any other personnel who might be affected.
c. On units where dose reduction pulsed fluoroscopy is available, its use is recommended.
d. For CT guided biopsies, lowering the mAs and/or increasing slice thickness can substantially reduce radiation dose without compromising the procedure.

B. Physiologic Monitoring and Resuscitation Equipment

1. Appropriate equipment should be present to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities using moderate sedation, a pulse oximeter should be available. (See the ACR–SIR Practice Guideline for Sedation/Analgesia.)

2. There should be ready access to emergency resuscitation equipment and drugs, to include the following: a defibrillator, oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-valve-mask apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine overdose, bradycardia, and ventricular dysrhythmias should also be readily available. Resuscitation equipment should be monitored and checked on a routine basis in compliance with institutional policies.

3. Any procedure performed using MRI guidance must have MRI safety compatible emergency resuscitation equipment available.

4. Appropriate emergency equipment and medications must be immediately available to treat procedural complications or adverse reactions associated with administered medications. The equipment should be monitored and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and/or sizes in the patient population.

C. Acute Care Support

Although complications of PNB only rarely require urgent surgery, some of these procedures should be performed in an environment where surgical intervention can be instituted promptly. Ideally, this would be a facility with adequate surgical, anesthesia, and ancillary support. When these procedures are performed in a freestanding center, detailed protocols for the rapid transport or admission of patients to an acute-care hospital should be formalized in writing.

D. Patient Care

The requested examination should be specific to body site and side, if appropriate.

1. Preprocedural care

a. The physician performing the procedure must have knowledge of the following:
   i. Clinically significant history, including indications for the procedure and any related preprocedure imaging.
   ii. Clinically significant physical examination findings, including an awareness of clinical or medical conditions that may necessitate specific care**,** such as preprocedure antibiotics or other measures.
   iii. Possible alternative methods, such as other imaging modalities, serologic analysis, or surgery, to obtain the desired diagnostic information or therapeutic result.

b. Informed consent must be in compliance with all state laws and should comply with the ACR–SIR Practice Guideline on Informed Consent for Image-Guided Procedures.

2. Procedural care

a. Adherence to the Joint Commission's current Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings, including bedside procedures.
The organization should have processes and systems in place for reconciling differences in staff responses during the "time out."
b. During the use of fluoroscopy, the physician should use exposure factors consistent with the ALARA radiation safety guidelines.
c. Nursing personnel, technologists, and those directly involved in the patient's care during PNB should have protocols for use in standardizing care. These should include, but are not limited to:
   i. Equipment needed for the procedure and its commonly related complications.
   ii. Patient monitoring.
d. Protocols should be reviewed and updated periodically.

3. Postprocedural care

a. Orders for postprocedure patient care should include frequency of obtaining vital signs and discharge instructions. Discharge instructions should include contact information about an appropriate resource that the patient or his or her representative can call to ask questions or express concerns about the development of complications or other issues.
b. Specific anatomic considerations
   i. Thoracic cavity: pulmonary and appropriate imaging assessment for the presence of pneumothorax.
   ii. Peritoneal and other solid organ biopsies: appropriate imaging and/or laboratory studies to evaluate for acute complications when indicated.

E. Specifics of the Procedure

1. All image-guided PNB procedures are performed for specific indications, and they should be tailored accordingly.
2. The physician should be aware of the various types of aspiration and core cutting needles that are available.
3. The physician should be aware of the diagnostic possibilities and request the appropriate laboratory studies.
4. Prior consultation with pathology may be useful in selected cases.
5. The postinterventional procedure note should include the names of the operator and assistant, specifics about the procedure, complications if any, medication or drugs used, condition of the patient, and disposition. Notification of the referring physician is highly recommended if significant complications occurred.

VI. DOCUMENTATION

Reporting should be in accordance with the ACR–SIR Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures.

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients

are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) http://www-pub.iaea.org/MTCD/Publications/PDF/p1531interim_web.pdf

Nationally developed guidelines, such as the ACR's Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Regular auditing of patient dose indices should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR web site (http://www.acr.org/guidelines).

Equipment performance monitoring should be in accordance with the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiological and Fluoroscopic Equipment.

IX. QUALITY IMPROVEMENT

While practicing physicians should strive to achieve perfect outcomes (e.g., 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Thus, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator that should prompt a review. Procedure thresholds or overall thresholds refer to a group of indicators for a procedure (e.g., major complications). Individual complications may also be associated with complication-specific thresholds.

When measures such as indications or success rates fall below a minimum threshold or when complication rates exceed a maximum threshold, a departmental review should be performed to determine causes and to implement changes, if necessary. For example, if the incidence of bleeding is one measure of the quality of image-guided PNB, then values in excess of the defined threshold should trigger a review of policies and procedures within the

department to determine the causes and to implement changes to lower the incidence for the complication. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Each department is urged to alter the threshold to higher or lower values as needed to meet its own quality improvement program needs.

A. Success Rates and Thresholds

Many variables will affect the eventual success of a PNB procedure. These include the number of samples obtained, the size of the target abnormality, the organ system in which biopsy is performed, the availability of an on-site cytopathologist [6], the experience of the institution's pathology staff, the imaging equipment available, and the skill of the operating physician.

Table 1 lists the success rates and suggested thresholds for PNB.

Table 1
Success Rates of PNB [7-29]

PNB Site	Reported Range of Success (%)	Pooled Mean Success (%)	Suggested QI Threshold (%)
Thoracic/pulmonary [7-15]	77-96	89	75
Musculoskeletal [16-23]	76-93	82	70
Other Sites [24-29]	70-90	89	75
Overall	70-90	85	75
Note: – QI = quality improvement.			

From Gupta S, Wallace MJ, Cardella JF, Kundu, S, Miller DL, Rose SC; Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for percutaneous needle biopsy. *J Vasc Interv Radiol* 2010; 21: 969-975 [30].

The range of successful biopsies may vary depending on the mix of organ systems, the size and location of lesions, and the overall condition of patients who are sampled. A nondiagnostic specimen means is one in which the tissue sample is inadequate for pathologic determination of whether the specimen is benign, malignant, or representative of the organ being biopsied.

B. Complication Rates and Thresholds

Complications can be stratified on the basis of outcome. Major complications result in admission to the hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (see Appendix A). The complication rates and thresholds presented refer to major complications, unless otherwise noted. Indicator thresholds may be used to assess the efficacy of quality improvement programs.

The complications of percutaneous biopsies are divided into 2 types: generic and organ-specific. Generic refers to complications that are common to all biopsies. The major generic complications include bleeding, infection, perforation, and unintended organ or nerve injury [31]. Clinically significant bleeding is infrequent, although relative bleeding risks increase with increasing needle size, use of cutting needles, and vascularity of the organ or lesion biopsied (i.e., renal and liver biopsies, hypervascular lesions) [8,32]. Infection as a result of biopsy is also rare. Injury may occur to the target organ or to a nearby organ that is traversed by the needle. Injuries of this type require further interventions in fewer than 2% of patients [33-35]. How a given complication is managed clinically is a major predictor of the clinical outcome of a given patient and should be included in the oversight of complications of percutaneous biopsies.

Organ-specific complications are those that are only associated or most commonly associated with biopsy of a specific organ. For example, pneumothorax is most commonly associated with lung biopsy but can occur during

vertebral, rib, liver, spleen, adrenal, kidney, and breast biopsies or aspirations. Other complications may occur, but rarely require therapy. These include hematuria after renal or prostate biopsy and hemoptysis after lung biopsy. Perforation may be considered organ-specific.

The following table (Table 2) lists the reported rates of given complications and suggested thresholds that should prompt a review when exceeded. In addition, there are certain complications that are almost always associated with a single organ [36]. Very rare complications, such as hypertensive crisis after adrenal biopsy, pancreatitis, and tumor seeding of the needle tract [37,38] are not given thresholds. Each major incident should be investigated as appropriate.

Table 2
Complication Rates and Suggested Thresholds for Nonthoracic PNB [28,34,36,38-78]

Major Complication	Complication Rates (%)	Suggested QI Threshold (%)
Bleeding requiring transfusion or intervention		
Solid organ*		
Kidney [39,41-55]		
Large caliber needle (>18 gauge)	2.7-6.6	10
Small caliber needle (≤18 gauge)	0.5-2.8	5
Liver [36,45,56-64]	0.3-3.3	5
Spleen [65-69]	0-8.3	10
Other [28,34]	0.1-3	6
Tract seeding [34,38,40,70-78]†	0.3.4	5
Pneumothorax requiring chest tube for Nonpulmonary/mediastinal biopsy	0.5	1

Note: - QI = quality improvement.
*Data based on studies involving at least 200 patients.
†Most of the literature is related to needle tract seeding after percutaneous biopsy of hepatocellular carcinoma. Data based on studies involving at least 100 patients.

From Gupta S, Wallace MJ, Cardella JF, Kundu, S, Miller DL, Rose SC; Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for percutaneous needle biopsy. *J Vasc Interv Radiol* 2010; 21: 969-975 [30].

Lung and pleural biopsy: There are special considerations for classifying major versus minor complications requiring chest tube management after lung biopsy resulting in the development of a pneumothorax. Special note is also made that there are lung biopsies during which planned placement of a chest tube is accepted for the successful completion of the procedure. Placement of a chest tube in these settings therefore should not be considered a complication. [9,35,79-86]

Table 3
Complication Rates and Suggested Thresholds for Transthoracic PNB [8,9,79-81,83,87-97]

Complication	Complication Rate (%)	Suggested QI Threshold (%)*
Major		
Hemoptysis requiring hospitalization or specific therapy transthoracic biopsy [80,81]	0.5	2
Thoracostomy tube placement requiring prolonged admission, catheter exchange, or pleurodesis [87,88]	1-2	3

Complication	Complication Rate (%)	Suggested QI Threshold (%)*
Major		
Air embolism [81,89]	0.06-0.07	<0.1
Minor		
Pneumothorax [8,9,79,83,90-97]	12-45	45
Thoracostomy tube placement [8,9,79,87,90-97]	2-15	20
Note – QI = quality improvement *Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Exceeding a suggested QI threshold should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence for the complication.		

From Gupta S, Wallace MJ, Cardella JF, Kundu, S, Miller DL, Rose SC; Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for percutaneous needle biopsy. *J Vasc Interv Radiol* 2010; 21: 969-975 [30].

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a larger volume than most individual practitioners are likely to treat. Generally the complication-specific thresholds should be set higher than the complication-specific reported rates listed above. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient series (e.g., early in a quality improvement program). In this situation, an overall procedural threshold is more appropriate for use in a quality improvement program.

In Table 4 below**,** the suggested threshold value is supported by the weight of literature evidence and panel consensus.

Table 4
Overall Complication Threshold

Overall Procedure	Suggested QI Threshold (%)*
All major complications resulting from image-guided PNB*	2
*The threshold for overall major complications should be used when the individual practice performs a broad spectrum of biopsies and no particular biopsy site or type dominates the experience. This threshold is based on the premise that uncomplicated thoracostomy tube placement for management of pneumothorax is considered a minor complication.	

From Gupta S, Wallace MJ, Cardella JF, Kundu, S, Miller DL, Rose SC; Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for percutaneous needle biopsy. *J Vasc Interv Radiol* 2010; 21: 969-975 [30].

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Appendix A

Society of Interventional Radiology Standards of Practice Committee
Classification of Complications by Outcome

Minor Complications

A. No therapy, no consequence.
B. Nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

C. Require therapy, minor hospitalization (<48 hours).
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours).
E. Permanent adverse sequelae.
F. Death.

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*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

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January 29, 2014

Barbara Levy, MD
Chair, AMA Specialty Society RVS Update Committee
Relative Value Systems
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515 N. State Street
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Re: Tab 34 Moderate Sedation

Dear Dr. Levy,

On behalf of the American Nurses Association, we appreciate the opportunity to participate and comment on the RVU recommendations for the CPT codes for Moderate Sedation Services, contained in Tab 34. ANA members include registered nurses (RNs) who provide patient monitoring following moderate level sedation.

We have reviewed and support the RVU and practice expense recommendations for Tab 34. After careful review of current practice competencies for registered nurses, the RN is the only staff type permitted to monitor patients who have undergone moderate level sedation. The RN is needed to assess the patient and determine when discharge is appropriate. This is a nurse function and cannot be delegated to a licensed practical nurse (LPN). This staff type requirement applies to both facility and nonfacility settings when performing these high-risk procedures.

We fully support the recommended work RVUs; pre, intra, and post times; as well as the recommended practice expenses applicable to this code.

Sincerely,

W Bryan Sims, DNP, APRN-BC, FNP
RUC HCPAC Advisor
RUC PE Subcommittee Member
American Nurses Association