Coding Change Application

Laboratory Tests
American Medical Association, Current Procedural Terminology (CPT®)

Application Submission Requirements

All CPT code change applications are reviewed and evaluated by AMA staff, the CPT/HCPAC Advisory Committee, and the CPT Editorial Panel. Strict conformance with the following is required for review of a code change application:

- Submission of a complete application, including all necessary supporting documents;
- Adherence to all posted deadlines;
- Cooperation with requests from AMA staff and/or Editorial Panel members for clarification and information; and
- Compliance with CPT Statement on Lobbying. (press "Ctrl" key and click link)

Application Review Links (Press "Ctrl" key and click link)

- Applicant's Name
- Question 1
- Descriptor
- Typical Patient Description

Laboratory Test Application Specific Requirements

The information provided in this application will be reviewed by members of the AMA CPT Advisory Committee (national medical specialty societies seated in the AMA House of Delegates), the AMA Health Care Professional Advisory Committee (limited license practitioners), and the College of American Pathologists Coding Caucus (American Medical Association, Advanced Medical Technology Association, American Association for Clinical Chemistry, American Clinical Laboratory Association, American Society for Clinical Pathology, American Society of Cytopathology, College of American Pathologists, National Association of Medical Examiners, United States & Canadian Academy of Pathology, Clinical Laboratory Management Association, American Society for Microbiology, and American Association of Bioanalysts).

Further, the information provided in this application is confidential and proprietary and will only be used pursuant to participation in the Current Procedural Terminology (CPT) Process.

General Criteria for Category I and Category III Codes

All Category I or Category III code change applications must satisfy each of the following criteria:

- The proposed descriptor is unique, well-defined, and describes a procedure or service which is clearly identified and distinguished from existing procedures and services already in CPT;
- The descriptor structure, guidelines and instructions are consistent with current Editorial Panel standards for maintenance of the code set;
- The proposed descriptor for the procedure or service is neither a fragmentation of an existing procedure or service nor currently reportable as a complete service by one or more existing codes (with the exclusion of unlisted codes). However, procedures and services frequently performed together may require new or revised codes;
- The structure and content of the proposed code descriptor accurately reflects the procedure or service as typically performed. If always or frequently performed with one or more other procedures or services, the descriptor structure and content will reflect the typical combination or complete procedure or service;
- The descriptor for the procedure or service is not proposed as a means to report extraordinary circumstances related to the performance of a procedure or service already described in the CPT code set; and
- The procedure or service satisfies the category-specific criteria set forth below.

Category Specific Requirements

A. Category I Criteria

A proposal for a new or revised Category I code must satisfy all of the following criteria:

- All devices and drugs necessary for performance of the procedure or service have received FDA clearance or approval when such is required for performance of the procedure or service;
- The procedure or service is performed by many physicians or other qualified health care professionals across the United States;
- The procedure or service is performed with frequency consistent with the intended clinical use (i.e., a service for a common condition should have high volume, whereas a service commonly performed for a rare condition may have low volume);
- The procedure or service is consistent with current medical practice;
- The clinical efficacy of the procedure or service is documented in literature that meets the requirements set forth in the CPT code change application.

B. Category III Criteria

The following criteria are used by the CPT/HCPAC Advisory Committee and the CPT Editorial Panel for evaluating Category III code applications:

- The procedure or service is currently or recently performed in humans, **AND**

At least one of the following additional criteria has been met:

- The application is supported by at least one CPT or HCPAC advisor representing practitioners who would use this procedure or service; **OR**
- The actual or potential clinical efficacy of the specific procedure or service is supported by peer reviewed literature which is available in English for examination by the Editorial Panel; **OR**

There is:

a) at least one Institutional Review Board approved protocol of a study of the procedure or service being performed,
b) a description of a current and ongoing United States trial outlining the efficacy of the procedure or service, or
c) other evidence of evolving clinical utilization.

Cover Sheet for CPT® Coding Change Application

It is recommended that Applicants consult with national medical specialties and other qualified healthcare professional organizations that will typically provide the proposed procedure(s)/service(s) requested in this application to obtain comments on the type of work and potential for development of relative value units (RVUs) by the AMA Specialty Society RVS Update Committee (RUC). With recognition of scheduling needs of the specialty societies, when assistance from a specialty society will be sought, it is highly recommended that the Applicant plan for enough time for scheduling such discussions in advance of the application deadline to avoid violation of the AMA Statement on Lobbying. Interested national specialty organizations may have deadlines prior to the CPT application submission deadline to allow for application review and comment.

Date:	

Change Requested by:

Name(s):			
Organization:			
Address:			
City:		**State:**	**Zip Code:**
Telephone:			
Email:			

Please include this cover sheet with your application.

Notice of Potential Review by Interested Parties

An "Interested Party" is an individual or entity that may have a legitimate interest or may potentially be impacted by the CPT Editorial Panel's decision related to this application, as determined by the AMA. If recognized by the AMA, an Interested Party may request review of your application in advance of the CPT Editorial Panel meeting. You will be notified of the identity of any Interested Party recognized by the AMA with respect to this application. The application fields indicated below (including supporting documentation) will be provided to an Interested Party. Fields not identified below will not be shared with Interested Parties.

- Applicant (both the individual's and organization's identity)
- All information in sections 3 and 4 (FDA, HDE, rationale, code descriptor additions/deletions/revisions)
- Current Code Justification
- Site of Service
- Diagnosis/Condition for treatment
- Prevalence of Disease
- Specialties and Sub-Specialties that perform the Service
- Clinical Vignette/Description of patient
- Description of Procedure
- Submitted Literature and other supporting documentation

☐ I, the Applicant, acknowledge and agree.

CPT Confidentiality Agreement

In consideration of the permission granted to me to participate in the CPT code development process, including submission of this code change application and participation on or attendance at meetings of the CPT Editorial Panel ("Panel"), the CPT Advisory Committee, the Health Care Professionals Advisory Committee, the CPT Assistant Editorial Board, and ad hoc and/or standing workgroups and committees established by the Panel (each a "Meeting" and collectively "Meetings"), I, the Applicant, agree to the following:

1. I will maintain as confidential any and all materials and information that I obtain in connection with my participation in the CPT code development process, attendance at or participation in any Meeting, including but not limited to the following information, which shall collectively be considered "Confidential Information" and proprietary to the AMA:
    - Meeting materials that are made available by the AMA, including agendas and code change applications;
    - CPT codes and modifiers, text descriptors, cross references, and guideline language that have not yet been published by the AMA in any form, including in print or online, as well as content scheduled for publication in the CPT Assistant or other AMA coding publications or products ("Publication"); and
    - any information disclosed or discussed at a Meeting, and the identity and affiliation of the individual who provided the information.

The foregoing information shall be considered Confidential Information regardless of the format or forum by which it is provided to or obtained by the undersigned including but not limited to oral, electronic or print media.

2. I will use Confidential Information only in connection with my participation in the code development process and the Meeting. I will not disclose, distribute or publish Confidential Information to any individual or entity in any manner whatsoever, and I will not publish or authorize anyone else to publish Confidential Information in any Web posting, social media, article, newsletter, press release, publication, or other communication; provided, however, when participating in the code development process and Meeting as an authorized representative of or on behalf of a company, society or other legal entity, I, as an individual, understand that I am permitted to disseminate Confidential Information to appropriate individuals in that organization, for internal use within such organization solely in connection with such organization's coding activities. Further, I understand that I am permitted to disclose non-Confidential Information.

3. I will not use audio or video recording or photographic device in any manner during a Meeting to record or to copy Confidential Information. I will not remove any notices of copyright, trademark, confidentiality or other conditions on materials obtained by me or take any other action to circumvent the purpose and intent of this Confidentiality Agreement.

4. I acknowledge that the Panel can modify or eliminate a CPT code or the language or guidelines associated with a code at any time up to the date of final Publication of the CPT code set. Panel actions are not final until distribution of the CPT code set (on or before August 31 of each year). I acknowledge that the early release of Panel actions and any related information can cause significant disruption and confusion for physicians, patients, payers and third parties and could cause irreparable injury to the AMA and others. I understand however, that I am permitted to disclose and publish the limited information contained in the Summary of Panel Action document that is posted to the AMA public website within 30 days of each Panel meeting. I understand that, prior to AMA Publication, any information that I publish beyond that contained in the Summary of Panel Action document will be considered a violation of this Confidentiality Agreement.

5. I understand that Confidential Information does not include information that (a) is already in my possession not as a result of any breach of confidentiality by myself or any third-party, (b) is publicly available other than through breach of these or other confidentiality obligations, (c) is received by me from a third-party if such third-party was authorized to release the information and is not in breach of any confidentiality obligations, or (d) is subject to Publication or other disclosure by the AMA.

6. Violators of this Agreement may be barred from future Meetings or otherwise sanctioned.

7. This Confidentiality Agreement is not exclusive, and other confidentiality or non-use requirements, such as those imposed by the RVS Update Committee, and other actions and remedies, including third-party remedies and the AMA's right to seek injunctive relief, may apply to the information that I have access to as the result of my participation in the code development process and Meeting.

8. I, the Applicant, agree that the terms of this Confidentiality Agreement are binding on me, individually, and on the company, society or other legal entity on behalf of which I am an authorized representative. I understand that the AMA is materially relying on this representation and certification.

☐ I, the Applicant, acknowledge and agree.

Copyright Assignment

All proprietary rights including copyright in and to CPT codes, modifiers, text descriptors, cross references, guideline language, parentheticals and other materials, created by submission of this code change application and through the CPT code development process shall be owned by the American Medical Association. By checking below, I acknowledge the AMA's proprietary rights including copyright and I hereby assign to the AMA any right, title and interest in and to such copyrightable works.

☐ I, the Applicant, acknowledge and agree.

Statement of Compliance with the CPT Conflict of Interest Policy

For convenience, key elements of the Conflict of Interest Policy applicable to each Applicant in his or her individual capacity and each Presenter are summarized below. Note that an application Preparer is a Presenter. The Conflict of Interest Policy in its entirety is controlling (please refer to the Conflict of Interest Policy for additional information):

1) ***General Rule Regarding Interests***. Each code change application Applicant and each Applicant-designee making a presentation to the Panel about a code change application ("**Presenter**"), shall disclose all Interests held by the Applicant or Presenter and his or her Immediate Family Members.

    a. ***Written Disclosures of Interests by Applicant and Each Presenter***. Written disclosures of all Interests must be made by each Applicant on a Statement of Compliance at the time of submission of the code change application. Written disclosures of all Interests must be made by each Presenter on a Statement of Compliance prior to the meeting of the Panel at which a Presenter will present his or her code change application.

    b. ***Oral Disclosure of Interests by Applicant and Each Presenter***. Oral disclosure of Interests that are directly related to a code change application that is pending before the Panel is required by an Applicant and Presenter prior to addressing the Panel about that application.

    c. ***Impact of an Interest***. Following written disclosure of all Interests of an Applicant or Presenter, or his or her Immediate Family Member, and oral disclosure of Interests that are directly related to a code change application that is pending before the Panel, the impacted individual is not restricted in any way in performing his or her role as an Applicant or Presenter.

2) ***Key Definitions*.**

    a. ***"Interest(s)"*** means the following activities of or roles held by an Applicant and Presenter or his or her Immediate Family Member (unless otherwise noted):

        i. *Employment* – The Applicant or Presenter's current employer, job title, description of role (in brief) and whether the employer is the applicant on the code change application that is pending before the Panel. This disclosure requirement does not apply to Immediate Family Members.

        ii. *Receipt of Value* – The Applicant or Presenter, or his or her Immediate Family Member, received any Value within the prior 24 months or anticipates receiving any Value in the next 24 months. The Value is separated into three categories:

            1. *Corporate* – The Applicant or Presenter, or his or her Immediate Family Member, is an owner, director or officer of; or an employee or agent who has decision-making authority in, a corporate entity, the Value of which will

or is likely to be impacted by the code change application that is pending before the Panel.

2. *Individual* – The Applicant or Presenter, or his or her Immediate Family Member, will or is likely to receive any Value based on the decision on the code change application that is pending before the Panel.

3. *Specialty Society* – The Applicant or Presenter, or his or her medical specialty society, will receive any Value for the Applicant or Presenter's consulting on, advising on or strategizing about the code change application that is pending before the Panel.

iii. *Developmental Interest* – The Applicant or Presenter, or his or her Immediate Family Member, has a Developmental Interest in the code change application that is pending before the Panel.

iv. *Other* - Any other interest that a reasonable person would consider relevant to or potentially impacting the judgment or decisions of the disclosing Applicant or Presenter in the context of Panel business.

3) ***Other Definitions***.

a. "***Applicant***" means each individual and corporate entity identified as an applicant or co-applicant on a code change application. For the purposes of the disclosure below, an Applicant must make a disclosure only in his or her individual capacity.

b. "***Developmental Interest***" means the Applicant and Presenter's, or his or her Immediate Family Member's, involvement in study or research development, execution of testing or studies, or authorship of published literature related to the code change application that is pending before the Panel and in connection with which such has received Value or a promise of future Value from a pharmaceutical, biological or medical device manufacturer outside of a research grant in which the individual's literature will be cited. Developmental Interest excludes the subject individual's membership on a safety or a monitoring committee (or its equivalent) for a research grant.

c. "***Immediate Family Member***" means a spouse, domestic partner, parent, child, brother or sister. Requirements for disclosure of interests of Immediate Family Members apply to the extent such interests are known by the disclosing person.

d. "***Presenter***" means an Applicant's designee to make an oral or written presentation to the Panel on a code change application. Presenter includes a Preparer who prepares all or a portion of a code change application for presentation to the Panel.

e. ***"Value"*** means money, goods or any other item or service of value, whether the same increases or decreases. Value is aggregate, and includes but is not limited, to:

i. Sales
ii. Intellectual property valuation, royalties or other rights
iii. Funding support, including grants

iv. Stock value, only if the stock is included in an actively managed personal investment account
v. Consulting fees
vi. Gifts including meals, paid travel and speaking bureau participation
vii. Fees or other compensation for speaking engagements, including honoraria
viii. Salary or salary support
ix. Expert testimony payment

Value excludes any payment or reimbursement of expenses received from a medical specialty society for services that are educational or generally applicable to all members of such society and that are otherwise not for the benefit of any individual of such society.

Disclose all Interests below:

INTERESTS

☐

- Identify all Interests held by you and your Immediate Family Members

☐ I affirm that I have read and understand the CPT Conflict of Interest Policy. Each of my, and my Immediate Family Members', Interests at this time are set forth below. I understand that I have a continuing obligation to comply with the CPT Conflict of Interest Policy and will update this form, as needed, during the course of the year and annually at the request of the Chair of the Editorial Panel.

Attestations

I hereby attest to each of the following:

1. I understand that my code change application will be evaluated by the CPT Editorial Panel, CPT/HCPAC Advisors, Members of Advisory Committees, as applicable, and AMA staff. I will timely cooperate with requests from the CPT Editorial Panel, CPT/HCPAC Advisors, committee members and AMA staff for clarification and information.
2. I understand that it is recommended that I consult with national medical societies and other qualified healthcare professional organizations that will typically provide the proposed procedure(s)/service(s) requested in this application to obtain comments on the type of work and potential for development of relative value units (RVUs) by the AMA Specialty Society RVS Update Committee (RUC) ***prior to the submission*** of this application to comply with the CPT Statement on Lobbying.
3. I understand that this application is not complete until I and the other co-Applicants and Preparers (if applicable) named on this code change application have electronically completed the **CPT Confidentiality Agreement**, the **Copyright Assignment** and a **CPT Conflict of Interest Policy Compliance Statement**. Failure to submit a complete application and the requested documentation within the requested timeframe will prevent AMA staff from processing my code change application. If the code change application is not submitted in time for the upcoming Panel meeting, or it is incomplete, I understand that my application will not be considered at the next Panel meeting, but that the application may be resubmitted for consideration by the Panel at a later date.
4. I understand that, after I submit this code change application, I may withdraw this application up until the time that the CPT Editorial Panel takes up the agenda item at a CPT Editorial Panel meeting. At that time, the application falls under the authority of the Editorial Panel, and may not be withdrawn.

   ☐ **I, the Applicant, acknowledge and agree.**

This form plays a vital role in maintaining and increasing the efficiency of the CPT process. This is a special form to be used to facilitate the review of coding change applications for laboratory test in any of the three categories of CPT Codes. As you fill out this form, consider the category of code change for which you are applying. For more information on these three categories, please see code change application form instructions. (Press "Ctrl" key and click link)

When requesting a new code, the entire form should be completed. When submitting a request for multiple new codes, a response should be provided for each new code. The Applicant may need to create additional lines and pages as needed. Refer to the code change application instructions if necessary. Once the application is completed, submit the form electronically to the AMA. (See information on submitting applications on the last page for instructions on uploading applications, literature supplements and other documents.)

You may withdraw your application up until the time that the CPT Editorial Panel takes up the agenda item at a CPT Editorial Panel meeting. At that time, the application falls under the authority of the Editorial Panel and may not be withdrawn. If the CPT Editorial Panel determines that additional information or evaluation is warranted, consideration of your application may be tabled until later during that meeting or postponed until time certain (a specific future CPT meeting) or to time uncertain.

Code Descriptor Formatting Instructions

When entering code information on this application, please use the formatting shown below. When **ADDING** codes, this will require specifying the recommended terminology (code descriptor) for the proposed CPT code and the placement of the proposed code in the current text of CPT (list section, subsection as illustrated below). When requesting a code **REVISION** you should use strike-pouts for deletions and underlining for additions/revisions (example: 33420 Valvotomy, mitral valve (~~commissurotomy);~~ closed heart). You may copy and paste the following symbols as appropriate:

- ● This symbol precedes a **new** code (example: ● 1234X)
- ▲ This symbol precedes a **revised** code (example: ▲12345)
- ✚ This symbol indicates an **add-on code** to be reported with another code (example: ✚12345)
- ☒ This symbol indicates codes that are **exemptions to modifier 51**, but have not been designated as CPT add-on procedures or services (example: ☒12345)
- ⚡ This symbol indicates codes that are **product pending FDA approval** (example: ⚡12345)
- # This symbol indicates codes that are **out-of-numerical sequence** (example: #12345)
- ★ This symbol indicates codes that are **telemedicine** (example: ★12345)

Example:

Surgery
Digestive System
Stomach
Incision

D12345 ~~Old procedure~~

(Code 12345 has been deleted. To report, see 1234X1-1234X2)

⊙●1234X1 New procedure first

✚⊙●1234X2 each additional (list separately in addition to primary procedure)

(Report code 1234X2 in conjunction with code 1234X1)

1. Does this laboratory procedure involve the use of reagents or procedures that require approval or clearance from the Food and Drug Administration (FDA)?

   ☐ Yes (Go to Question 2)

   ☐ No (Go to Question 3)

2. Has FDA approval or clearance been received for the test or reagents for the use that you are proposing? Please specify any condition of approval (e.g., 510K). If Yes, submit documentation of the FDA approval with the application.

   ☐ Yes

   ☐ No (If no, provide details of why some necessary element of this service has not received FDA)

   Click here to enter text.

3. Indicate the specific reasons why this code addition or change is necessary (rationale). Be specific about the reasons for this new test or test change application and avoid answering "no code is available" or "need new code" as these responses are not informative. Describe why the test is different, if appropriate, in terms of the analyte evaluated and the methodology employed.

   Click here to enter text.

4. Following the Code Descriptor Formatting Instructions, specify the proposed new, revised and/or deleted codes, descriptors, inclusionary and exclusionary parentheticals and guidelines as applicable. List all current codes related to your request, not just the individual code changes. (Refer to the code change application instructions for more detailed information.)

   * If requesting a new code within the Path/Lab section, specify the recommended methodology (code descriptor) for the proposed CPT code. Specify the placement of the proposed code in the current test of CPT (e.g., where in the 80000 series should the test be placed – e.g., Hematology and Coagulation (85002-85999)). Also list synonyms or other technical names that may be used for the test or testing procedure (e.g., •87X17 Pinworm exam (e.g., cellophane tape prep).

   Click here to enter text.

5. Please specify the volume of test(s) performed annually.

   Click here to enter text.

6. Is the test(s) you are proposing performed by a large number of laboratories (e.g. reference laboratories, hospital laboratories, physician office laboratories)?

   ☐ Yes

   ☐ No

   Please specify the number of laboratories performing the test(s).

   Click here to enter text.

7. Has the clinical efficacy and utility of the test which you are proposing been published and well documented (i.e., peer reviewed U.S. literature, referable to the typical patient population who would benefit from the test(s))?

   ☐ Yes

   ☐ No

8. Please indicate which CPT or HCPCS Level II code(s) are currently being used to report the proposed test(s). Indicate if either a less specific code or unlisted code are currently being used to code for this service.

   Click here to enter text.

9. Why is (are) the present codes in the previous question inadequate to describe the test? If a test represents a variation in a testing methodology or a new analyte employing an existing methodology, do the existing codes describe the test but not to the same level of specificity?

   Click here to enter text.

10. Identify the major differences between the proposed code change and any other related codes already existing in CPT.

    Click here to enter text.

11. Are there any codes existing or proposed that are an integral part of the proposed code? This list should include CPT codes for all tests that, if coded in addition to the code(s) for this test(s), would represent unbundling or double billing.

    Click here to enter text.

12. What are the diagnoses, symptoms and/or conditions that the test seeks to diagnose or follow?

    Click here to enter text.

13. What are the incidences or prevalence of the diagnoses, symptoms and/or conditions that the test seeks to diagnose or follow?

    Click here to enter text.

14. How long (e.g., years) has the test been offered to patients? This information can be obtained from the medical literature (preferably United States peer-reviewed literature), funded studies (please indicate whether these studies are funded by the manufacturer, the government, or another agency). Literature can be cited in bibliographical format. For the CPT Editorial Panel to add a Category I code, the documentation must substantiate that the test(s) are widely used and accepted.

    Click here to enter text.

15. Has this test been classified under CLIA?

    ☐ Yes, as a high complexity test

    ☐ Yes, as a moderate complexity test

    ☐ Yes, as a waived test

    ☐ No

    ☐ Not applicable. Specify why.

    Click here to enter text.

    ☐ Don't Know

16. If you are recommending a new code, please estimate the percentage of the testing currently performed using existing codes that would now be coded using the proposed new code(s).

    Click here to enter text.

17. Are you aware of any practice guidelines or policy statements about these parameters regarding the use of this test to diagnose or manage patients with specific diseases? If yes, Please provide copies of such.

    ☐ Yes

    ☐ No

    ☐ Don't Know

    Click here to enter text.

18. Of the CPT and or Health Care Professional Advisory Committee specialties listed in CPT, please identify the specialties or subspecialties that might be impacted by the test(s) proposed, either because they might perform the test or use the results.

    Click here to enter text.

19. What is the typical site of service where this test is performed?

    ☐ Independent Laboratory

    ☐ Physician's Office Laboratory

    ☐ Hospital Inpatient Laboratory

    ☐ Emergency Medical Transport Facility

    ☐ Home Health Service Laboratory

    ☐ Other

    If Other, please specify

    Click here to enter text.

20. Provide a clinical vignette that describes the typical patient that would receive this test. The vignette should include any special specimen collection and storage needs, analytic requirements, or reporting requirements.

    Click here to enter text.

21. For each proposed NEW and/or REVISED code(s), provide a brief description of the procedure/service performed Please refer to the sample format and examples of appropriate descriptions of service below. It is important that the description of the service make apparent the services that are integral or separately reported. If the description includes services that are reported separately, please clearly indicate this separate reporting.

    Click here to enter text.

22. Please forward the following documentation with your application, if appropriate. If not appropriate, please indicate why:
    a) A copy of the manufacturer's product insert that accompanies the test(s)
    b) A copy of a standard CLSI format procedure from a licensed, accredited, or certified clinical laboratory that currently employs the test.
    c) Up to three articles (preferably United States peer-reviewed literature) that describe the test and test performance. Do not include references that describe the underlying disease or diagnostic condition for which the test is ordered.

    Click here to enter text.

23. Please provide electronic (PDF or Word documents) copy(s) (and internet addresses, if available) of literature to support your application, and cite the author, title, journal, year, volume and page(s) in the "Publication Details and Attributes Grid" (PDA grid) that follows. Each item of submitted literature shall be identified in the PDA grid according to each of the 4 following requirements:

    1. Identify the Level of Evidence by selecting a level from the LOE table below;
    2. Identify whether this is a U.S. based journal or a non-U.S. based journal, and identify whether the population studied is U.S. or non-U.S. or both;
    3. Identify the number of patient studies (total of all group(s) including controls) and indicate whether study is a prospective study;
    4. Provide a concise "relevance statement".

General Guidelines for inclusion of the articles are noted in the following:

1. Abstracts are allowed to supplement application but will not be accepted in substitution of full length journal articles.

2. Foreign journals will be permitted if published in the English language.

3. List up to 5 references, of which at least 1 report the procedure/service in a U.S. patient population. Of these, at least 2 articles must report different patient populations or have different authors (no overlapping patient populations or no overlapping authors).

4. At least 1 of the publications meets or exceeds the criteria for evidence level III (i.e. obtained from well-designed, non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies). However, code change applications requesting editorial changes to existing Category I codes and applications for bundled codes to describe unchanged existing Category I services (when provided together) need not meet this requirement.

24. For Category III codes, please reference studies or research performed by national organizations if available.

    The following is used as formalized criteria by the CPT Advisory Committee and the CPT Editorial Panel for evaluating Category III code applications, and includes identification of the following elements as guidelines for establishment of a Category III code:

    - A protocol of the study or procedures being performed;
    - Support from the specialty societies who would use this procedure;
    - Availability of U.S. peer-reviewed literature for examination by the CPT Editorial Panel;
    - Descriptions of current U.S. trials outlining the efficacy of the procedure.

Level of Evidence Table – LOE

Level	Type of evidence (based on AHCPR 1992)
Ia	Evidence obtained from meta-analysis of randomized controlled trials
Ib	Evidence obtained from at least one randomized controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomization
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 control studies
IV	Evidence obtained from case reports or case series
V	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Publication Details and Attributes (PDA) Grid Code #_____					
References	**Level of Evidence Based on LOE Table**	**US or Foreign Peer Reviewed**	**US or Foreign Population Studied**	**Prospective Study?**	**Total Patients Studied**
Article #1 (Author, Title, Journal, Year, Volume and Pages)	*Insert Level #*	☐ **US** ☐ **Foreign**	☐ **US** ☐ **Foreign** ☐ **Both** (If answered both: Provide specific % of patients **OR** # of patients for both regions) **Population %** **U.S. Foreign** **%____ %____** **Population #** **U.S. Foreign** **#____ #____**	☐ **Yes** ☐ **No**	*Insert #*
Provide brief description regarding relevance to CCP*					
Article #2 (Author, Title, Journal, Year, Volume and Pages)	*Insert Level #*	☐ **US** ☐ **Foreign**	☐ **US** ☐ **Foreign** ☐ **Both** (If answered both: Provide specific % of patients **OR** # of patients for both regions) **Population %** **U.S. Foreign** **%____ %____** **Population #**	☐ **Yes** ☐ **No**	*Insert #*

			U.S. Foreign #____ #____		
Provide brief description regarding relevance to CCP*					

Article #3 (Author, Title, Journal, Year, Volume and Pages)	*Insert Level #*	☐ **US** ☐ **Foreign**	☐ **US** ☐ **Foreign** ☐ **Both** (If answered both: Provide specific % of patients **OR** # of patients for both regions) **Population %** **U.S. Foreign** **%____ %____** **Population #** **U.S. Foreign** **#____ #____**	☐ **Yes** ☐ **No**	*Insert #*
Provide brief description regarding relevance to CCP*					

Article #4 (Author, Title, Journal, Year, Volume and Pages)	*Insert Level #*	☐ **US** ☐ **Foreign**	☐ **US** ☐ **Foreign** ☐ **Both**	☐ **Yes** ☐ **No**	*Insert #*

			(If answered both: Provide specific % of patients **OR** # of patients for both regions) **Population %** **U.S. Foreig** **%____ %____** **Population #** **U.S. Foreig** **#____ #____**		
Provide brief description regarding relevance to CCP*					
Article #5 (Author, Title, Journal, Year, Volume and Pages)	*Insert Level #*	*Indicate US or Foreign*	☐ **US** ☐ **Foreign** ☐ **Both** (If answered both: Provide specific % of patients **OR** # of patients for both regions) **Population %** **U.S. Foreig** **%____ %____** **Population #**	☐ **Yes** ☐ **No**	*Insert #*

			U.S. **Foreign** #____ #____		
Provide brief description regarding relevance to CCP*					

*** For each article cited, please provide a brief description of why the specific literature reference is relevant to the CCP (e.g. "this is the hallmark double blinded controlled study establishing the value of the procedure/service", "this is a case report describing the procedure/service in detail", or "this is an opinion statement from a respected authority in the field").**

25. Have you found any publications in addition to those cited in the CCP which offer conflicting data or different opinions, and that you feel are important for Editorial Panel consideration in evaluating this CCP? If so, please provide the literature reference, level of evidence, the reason that you consider the publication(s) relevant, and why you excluded them from the articles cited in 24.

Reference	Level of Evidence based on LOE Table	Brief description regarding relevance and why you excluded from articles in 26a.
Article #1 *(List Author, Title, Journal, Year, Volume, Pages)*	*Indicate Level #*	*Describe:*
Article #2 *(List Author, Title, Journal, Year, Volume, Pages)*	*Indicate Level #*	*Describe:*
Article #3 *(List Author, Title, Journal, Year, Volume, Pages)*	*Indicate Level #*	*Describe:*
Article #4 *(List Author, Title, Journal, Year, Volume, Pages)*	*Indicate Level #*	*Describe:*

26. Other Comments

Click here to enter text.

Final Attestations

By signing below, I, the Applicant, hereby attest to each of the following:

1. The information provided in this application is true, correct and complete, and, to the best of my knowledge, accurately depicts current clinical and or surgical practice;
2. I have read the CPT Statement on Lobbying, Criteria for Development and Evaluation of CPT Category I and Category III codes, CPT Code Application Instructions, CPT Editorial Panel Confidentiality Agreement, and CPT Application Process FAQs all referenced on the Applying for CPT Codes (press "Ctrl" key and click link) page and on related pages; and
3. I have authority to sign this application in both an individual and organizational capacity.

Signature	
Print Name	
Organization (if applicable)	
Date	

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If you have any questions concerning the requirements on the Coding Change Application, please consult with AMA staff prior to the submission of your application. An incomplete application may delay processing of your request and may cause it to be returned.

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