

Molecular Pathology Workgroup Meeting

February 3, 2012

Facilitator(s):

Mark Synovec, MD, CPT Editorial Panel

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Agenda

1. Introductions
2. Confidentiality agreements
3. Updates:
 - a. Panel actions of October 2011
 - b. Panel agenda of February 2012:
 - i. Tier 2a Subworkgroup (Tab 28, proposal #3780)
 - ii. Tier 1 (Tab 29, proposal #3776)
 - iii. Deletion of stacking codes (Tab 31, proposal #3775)
 - iv. Multianalyte Assays with Algorithmic Analyses (MAAA) (Tab 33, proposal #3842)
 - c. Tier 2b work product
4. Current work of Tier 2a Subworkgroup
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Panel Agenda October 2011: Tier 2a additions:

- 6 additional analytes to level 1
- 13 additional analytes to level 2
- 2 additional analytes to level 3
- 7 additional analytes to level 4
- 10 additional analytes to level 5
- 9 additional analytes to level 6
- 22 additional analytes to level 7
- 5 additional analytes to level 8

Panel agenda October 2011: Tier 2a Subworkgroup Proposal

- 6 additional analytes to level 1
- 13 additional analytes to level 2
- 2 additional analytes to level 3
- 7 additional analytes to level 4*
- 10 additional analytes to level 5
- 9 additional analytes to level 6
- 22 additional analytes to level 7
- 5 additional analytes to level 8

14
additions

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Tab 28, proposal #3780 (Tier 2 additions)

- 2 additional analytes to level 1
- 17 additional analytes to level 2
- 6 additional analytes to level 4 (and 1 modification)
- 13 additional analytes to level 5
- 30 additional analytes to level 6
- 26 additional analytes to level 7
- 10 additional analytes to level 8
- 6 additional analytes to level 9

Panel agenda October 2011: Tier 2a Subworkgroup Proposal

- 6 additional analytes to level 1
- 13 additional analytes to level 2
- 2 additional analytes to level 3
- 7 additional analytes to level 4*
- 10 additional analytes to level 5
- 4 additional analytes to level 6
- 22 additional analytes to level 7
- 5 additional analytes to level 8

110
proposed
additions



Tab 29, proposal #3776 (Tier 1 additions)

- AXXX2 *APC (adenomatous polyposis coli)* (eg, familial adenomatous polyposis [FAP], attenuated FAP) gene analysis; full gene sequence
- AXXX3 known familial variants
- AXXX4 duplication/deletion variants



Tab 31, #3775- Deletion of “Stacking” codes

Issue #1

Addition of unlisted molecular pathology procedure code

Category I/Pathology and Laboratory/Tier 2 Molecular Pathology Procedures

81408 *Molecular pathology procedure, Level 9 (eg, analysis of >50 exons in a single gene by DNA sequence analysis)*

- 814X9 Unlisted molecular pathology procedure



Tab 31, #3775- Deletion of “Stacking” codes

Issue #2

Deletion of codes 83890-83914 and introductory guidelines related to these codes.

▶ (83890-83914 have been deleted. To report, see 81200-814X9) ◀



Tab 31, #3775- Deletion of “Stacking” codes

Issue #3

- Deletion of codes 88384-88386 and deletion of two parenthetical notes following code 88386.

~~88384 — Array based evaluation of multiple molecular probes; 11 through 50 probes~~

~~88385 ————— 51 through 250 probes~~

~~88386 ————— 251 through 500 probes~~

▶ (88384-88386 have been deleted. To report, see 81200-814X9) ◀



Tab 31, #3775- Deletion of “Stacking” codes

Issue #4

Deletion of all Genetic Testing Code Modifiers (Appendix I).

- ▶ (Appendix I – Genetic Testing Code Modifiers have been deleted, To report, see 81200-814X9) ◀



Tab 31, #3775- Deletion of “Stacking” codes

Issue #5

Revision and deletion of guidelines and cross references throughout CPT related to deletion of codes 83890-83914, 88384-88386, and Appendix I.



Tab 33, proposal #3842 (MAAAs)

- The proposed Category I MAAA code set will function like traditional CPT codes
- An proposed Administrative code list will also be maintained by CPT that:
 - As a minimum standard it is an analysis that is generally available for patient care.
 - The AMA will not review procedures in the administrative coding set for clinical utility.
- Neither proposed MAAA code set will be restricted solely to MoPath

Tab 33, proposal #3842 (MAAAs)

- “Multianalyte Assays with Algorithmic Analyses (MAAAs) are procedures that utilize multiple results derived from assays of various types, including molecular pathology assays, fluorescent in situ hybridization assays and non-nucleic acid based assays (eg, proteins, polypeptides, lipids, carbohydrates).”
- “Algorithmic analysis is then performed to derive a single result, reported typically as a numeric score or probability.”
- “MAAAs are typically unique to a single clinical laboratory or manufacturer.”

Tab 33, proposal #3842 (MAAAs)

- Code descriptor uses highly specific language including:
 - Disease type (eg, oncology, autoimmune, tissue rejection),
 - Material(s) analyzed (eg, DNA, RNA, protein, antibody),
 - Number of markers (eg, number of genes, number of proteins),
 - Methodology(ies) (eg, microarray, RT-PCR, ISH, ELISA),
 - Number of functional domains (if indicated),
 - Specimen type (eg, blood, fresh tissue, formalin-fixed paraffin embedded),
 - Algorithm result type (eg, prognostic, diagnostic),
 - Report (eg, probability index, risk score)
- Code descriptor will not have a proprietary name in the descriptor
- But a proprietary name will be listed in a CPT Appendix

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Tier 2B Subworkgroup


- Submitted a report to the MPWG and then to the CPT Editorial Panel Executive Committee for the creation of a Molecular Pathology Expert Panel, including ideas on structure and function of the group.
- The Panel approved the group in concept however modified the name to “Molecular Pathology Advisory Panel” (February 2011) and directed it’s creation, beginning as an ad hoc workgroup until they can propose a specific SOP for Panel review.
- A preliminary membership was created, utilizing core members of the MPWG, that were fully engaged in the Tier 1 and Tier 2a subworkgroups.



Initial Charge

1. Advise the Panel on the structure and function of a standing Advisory Group to perform the review functions.
2. Review Multi-Analyte Assays with Algorithmic Analyses (MAAAs).
3. Serve as the interim advisory group to advise and inform the Pathology Coding Caucus and the Panel of the results of review and coding recommendations of any molecular pathology applications submitted for each CPT Editorial Panel meeting.

(Note: It is not the purpose of the workgroup to create de novo new or revised code change applications, however, the work group may suggest alternative language with its comments)



(Ad Hoc) Molecular Pathology Advisory Group (MPAG)

- Had first meeting on 1/19/12
- Reviewed all MPWG proposals as well as other MoPath CCPs
- In the process of developing an SOP for the “mature” MPAG that will be sent to CPT-EC in May.
- Discussed strategic issues regarding CPT MoPath.
- Members serve AMA-CPT and do not represent societies or laboratories.

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Public Comments (06/11 report) presented a 10/11 mtg

- 30 commentors provided input that was divided accordingly:
 - Proposed new Tier 1 code(s) (2/0)
 - Proposed modifications of Tier 1 code(s) (18/6)
 - Proposed modifications of the definitions (5/2)
 - Proposed new Tier 2 code analyte(s) (340/??)
 - Proposed modifications of Tier 2 code analyte(s) (4/1)
 - Proposed modifications of the Tier 2 introduction (2/0)
 - Payment policy comments (n/a)
 - No proposals for MAAAs were received!

*Numbers are estimates

Tier 2a Subworkgroup

- To date have meet 69 times.
- Have approximately 95 more submissions to review from public comments
- Have already drafted 79 additions to Tier 2 for May meeting
- Have also identified another addition to Tier 1 that will be addressed in the May meeting:
 - *DMD (dystrophin)* (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed

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Duplication/deletion variants

How to appropriately include these when clinically appropriate?


- Search GeneTests database. If $\geq 10\%$ of disease alleles are associated with dup/del and ≥ 2 dup/dels are documented, place dup/del for analyte on Tier 2 list.

OR

- If BIOBASE HGMD® Professional database search identifies $\geq 10\%$ of disease alleles are associated with dup/del (gross deletion or insertion variants/total number of BIOBASE® variants reported) and ≥ 2 dup/dels are documented, place dup/del for analyte on Tier 2 list.

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Minimum analyte qualifications to be included in Tier 2 *(in addition to dup/del criteria)*

- Demonstrated relationship between biomarker and phenotype (ie, clinical validity)
- *Analysis is offered by a laboratory in the United States*


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Methodologic Clarification for Tier 2

- Although the root of the Tier 2 code contains examples of methodologies included that will be used for analyses in this code, this does not restrict the use of this code for other methodologies



Methodologic Clarification for Tier 2 (Example)

81400 Molecular pathology procedure, Level 1 (eg, identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis)

ACADM (acyl-CoA dehydrogenase, C-4 to C-12 straight chain, MCAD) (eg, medium chain acyl dehydrogenase deficiency), K304E variant

81401 Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)

ACADM (acyl-CoA dehydrogenase, C-4 to C-12 straight chain, MCAD) (eg, medium chain acyl dehydrogenase deficiency), common variants (eg, K304E, Y42H)

If your lab interrogates for *ACADM* common variants (K304E, Y42H) using gene sequencing you would still use **81401!**

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Limited (non-genome-wide) microarrays

- So what is the accepted definition of genome-wide and where should the division to individual MoPath codes be defined?
- Considerable debate by subworkgroup
- Additional debate by MPAG



Limited (non-genome-wide) microarrays

- Current direction
 - Create a specific coding solution for the handful of clinically useful “limited” microarrays.
 - A small sub-group of the subworkgroup will work to provide further clarity on this direction.

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Future plans Tier 2a Subworkgroup

- Finish Public Comment Review
- Complete (?) GeneTest analytes including reassessment of dup/del
- ?

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Transition to typical CCP submission process

- 3 separate (non-MPWG sponsored) non-infectious disease MoPath CCPs received for this meeting
- 3 separate (non-MPWG sponsored) infectious disease MoPath CCPs received for this meeting
- This will supplant the MPWG submissions in the future.



Transition to typical CCP submission process

CCPs will be reviewed by the MPAG prior to PCC review:

- MPAG will provide opinion on non-infectious disease MoPath CCPs that will be forwarded to the PCC and Editorial Panel
- MPAG may provide suggestions on infectious disease MoPath CCPs

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To Date

- 466 analyte-specific descriptors for MoPath services have been drafted by the MPWG, most are currently accepted for the CPT code set!

Special thank you to:

- AMA-CPT staff
- The MPWG Co-chairs
- All that have contributed to this Workgroup
- The “core” of the Tier 2a workgroup for their continued dedication!
- And,



David Mongillo, ACLA



Questions or comments?

Please contact us at:

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