Coding Change Application

Molecular Pathology Multianalyte Assays Algorithmic Analyses-
Genomic Sequencing Procedures
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

MAAA specific Requirements

Category I CPT code(s)

- Tier 1 Molecular Pathology procedures
- Tier 2 Molecular Pathology procedures
- Multianalyte Assays with Algorithmic Analyses (MAAAs)
- Genomic Sequencing Procedures (GSPs) and other Molecular Multianalyte Assays

Non-Category I Administrative MAAA code(s)

- Multianalyte Assays with Algorithmic Analyses (MAAAs)

This form plays a vital role in maintaining and increasing the efficiency of the CPT process. It identifies multiple pieces of information that are relevant to understanding the significance and need for a new code or codes. The CCP submission's unique identifier number is used to share the supporting data with the reviewers and CPT Editorial Panel.

When submitting a request for MAAAs, please consider whether you are applying for a Category I MAAA code or a non-Category I Administrative MAAA code. For more information on Category I codes, please see instructions below. (Press "Ctrl" and click the link)

Grouping multiple unrelated analytes or unrelated groups of analytes together in a single CCP can add unnecessary challenges in evaluating the supporting data and understanding the need for a particular code or codes. Hence, when submitting multiple analytes that are not performed as part of a panel for inclusion in CPT, please (1) complete a separate CCP for each analyte (or group of unrelated analytes), along with the relevant supporting literature or publications pertinent to each CCP; (2) provide specific information for tests that are clinically ordered and reported together with any relevant information about calculations that are used to combine the results of these tests (tests that require the use of statistical algorithms to achieve a risk score from the assay results should be requested in the MAAA category of tests).

When applying for a code for an individual analyte or gene, please report how often that individual analyte or gene is analyzed independently in your answer to question 3a. If the analyte or gene is predominantly analyzed as part of a panel, genomic sequencing procedure or multianalyte assay, do not submit a CCP for independent analysis of that analyte or gene, unless there is a clinical need for the individual analysis documented in peer-reviewed literature and cited in this application.

Please complete the entire form (insert additional lines and pages as needed). However, if you are applying for an Administrative MAAA code, responses to items 7, 8, 22, 24 and 26 are not required. Refer to the accompanying instructions if necessary. Once the application is completed, it should be submitted electronically. See instructions for submitting a code change application on the last page.

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.
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B. Parameters Specific for Category I Requirements for Molecular Pathology

The following criteria are used by the CPT/HCPAC Advisory Committee and the CPT Editorial Panel for evaluating Molecular Pathology applications for consistent application of Category I Criteria:

- In the case of Mendelian and somatic disorders, there is a demonstrated relationship between biomarker and phenotype (i.e., clinical validity)
- Biomarkers (e.g., SNPs) that have an association but not a proven causative effect to a known clinical phenotype(s) should have demonstrated clinical usefulness (e.g., high positive predictive value, high negative predictive value, directing therapy/management).
- Analysis is offered at least two U.S. laboratories are performing the analysis unless proprietary (e.g., intellectual property issues exist)
- The analysis involves $\geq$ 10 variants identified in unrelated families. Multiple reports of the same variant may be included.
- For dup/del assessment for Tier 2 code assignment the following guidelines will be used:

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

  OR

  If BIOBASE HGMD® Professional database search identifies >/=10% of variants that are associated with dup/del (gross deletion or insertion variants/total number of BIOBASE® variants reported), place dup/del for analyte on Tier 2 list.

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.

Requirement for Notification:

If you applying for a Category I MAAA code or for a listing in the Administrative MAAA code set and you are not the owner of the MAAA service or the lab that performs the MAAA, you must deliver a copy of this application to the company that owns or performs the procedure within 5 business days of submitting this application to the AMA. A copy of the communication should be forwarded to the AMA. The AMA encourages collaboration with the company/vendor source of the MAAA prior to submitting the application to assure accuracy in the descriptor and completeness of the information required by this application.

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. It can be used to submit a coding change application for either Category I or Category III CPT codes. For Pathology and Molecular Pathology codes, please utilize the appropriate application form. As you fill out the form, please consider which category of code change you are requesting. For more information and code criteria for the code categories, please see the code change application instructions. For other forms, see the AMA CPT website.
(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 the laboratory procedure involve the use of reagents or procedures that require approval or clearance from the Food and Drug Administration (FDA)? (not a strict requirement for code assignment)

   ☐ 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., 510(k)).

   ☐ Yes (Submitting documentation of the FDA approval or clearance is not required)

   ☐ No

   Click here to enter text.

3. Indicate the specific reasons why this code addition or change is necessary (rationale). Be specific about the need for this unique molecular pathology code. "No code is available" or "need new code" are not informative.

   Click here to enter text.

4. If this is a request for a new code, what code placement is being suggested?

☐ Tier 1 Molecular Pathology code (must meet Category I code criteria)

☐ Tier 2 Molecular Pathology code (must meet Category I code criteria except volume may be more limited)

If Tier 2 placement is being requested, please indicate the proposed placement (level 1-9) and provide rationale for this request below. Please also note similarity to procedure(s) already placed in the suggested tier level.

Click here to enter text.

☐ Other (e.g., infectious disease related molecular pathology procedure) – For this category please use the general laboratory test code change proposal form.

By selecting "Other", you have indicated that this code change request is a Laboratory Test application (instead of a MAAA application).

☐ Category I MAAA code (must meet Category I code criteria)

☐ Administrative MAAA Code (must have an analysis that is generally available for patient care) (a code contained in the Appendix O list that does not have a Category I code)

☐ Genomic Sequencing Procedure (GSP) or other Molecular Multianalyte Assay code (must meet Category I code criteria)

Click here to enter text.

5. 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 this is a request for a new code, specify the recommended terminology (code descriptor) for the proposed code. If proposing Tier 1 or Tier 2 placement, please use standardized nomenclature for these code sets (eg, gene name is represented by an abbreviation followed by the HUGO-approved full gene name italicized in parentheses, with proteins or diseases commonly associated with the genes listed as examples. Include gene variants as applicable.

   Examples:
   Tier 1: ASPA (aspartoaclyase) (eg, Canavan disease) gene analysis, common variants (eg, E285A, Y231X)

   Tier 2: *CAPN3 (Calpain 3)* (eg, limb-girdle muscular dystrophy [LGMD] type 2A, calpainopathy), full gene sequence

   Genomic Sequencing Procedures (GSP's) and other Molecular Multianalyte Assays: Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); genomic sequence analysis panel, must include sequencing of at least 9 genes including *FBN1, TGFBR1, TGFBR2, COL3A1, MYH11, ACTA2, SLC2A10, SMAD3, and MYLK.*

   Category I MAAA: Disease type, methodology, chemical analyzed, number of markers, functional domains (if indicated), specimen type, algorithm type, report type. (Please include the proprietary name and manufacturer)

   Administrative MAAA: Same code descriptor structure as Category I MAAA above. (Please include the proprietary name and manufacturer)

   Click here to enter text.

   Please indicate the Proprietary Name and Manufacturer Information:

   Click here to enter text.

6. Please indicate which CPT code(s) 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 is currently being used to code for this service.

   Click here to enter text.

7. Why is (are) the present code(s) (in the question above) inadequate to describe the procedure, and how will specificity created by this code change improve coding and test identification?

   Click here to enter text.

8. Identify the major differences between the proposed code change and any other related codes already existing in CPT. When the procedure described in the proposed code is similar to that of an existing code, please give a detailed explanation of the differences (e.g., testing methodologies, associated diseases).

   Click here to enter text.

9. Are there any codes existing or proposed that are an integral part of the proposed code? This list should include CPT codes (Molecular Pathology Tier 1 or Tier 2 or other) 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.

10. Please specify the volume of test(s) performed annually. (Please provide current and estimated future volumes as well as rationale on how these numbers were calculated.)

    Click here to enter text.

11. Is the suggested procedure/service a distinct service ordered by many clinicians across the United States? Please explain.

    Click here to enter text.

12. How many laboratories currently perform the analysis relevant to this proposal? Do you anticipate this number to change in the near future? If so, how?

    Click here to enter text.

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

    ☐ Yes

    ☐ No

14. Is (are) the test(s) for which you are proposing a code change used as a performance or quality measure by any national organization (e.g., evaluation of dopidogrel metabolism in a patient with history of acute MI)? If yes, specify the organization and name of the measure.

    ☐ Yes Organization: Click here to enter text.

    ☐ No Measure Name: Click here to enter text.

    ☐ Don't Know

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

    Click here to enter text.

16. 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.

17. How long (e.g., years) has the specific analysis been offered to patients? This information can be obtained from the medical literature (preferably United States peer-reviewed literature), and/or funded studies (please indicate whether these studies are funded by the manufacturer, the government, or another agency.) Literature can be cited in bibliographical format.

    Click here to enter text.

18. 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

19. Are you aware of any practice guidelines or policy statements 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

20. Do you represent a laboratory that performs the procedure represented in this proposal (answer required only if requesting a MAAA Category I or Administrative MAAA code)?

☐ Yes
☐ No

If yes, please identify the laboratory (full name, address and e-mail address).

Click here to enter text.

21. Have you contacted the laboratory that performs the procedure represented in this proposal (answer required only if requesting a MAAA Category I or Administrative MAAA code)?

☐ Yes
☐ No

If yes, please describe the interaction and note if the laboratory agrees with the code proposal.

Click here to enter text.

22. Please identify the specialty or subspecialty that will typically treat the diagnosis, symptoms or condition that the test seeks to identify.

Click here to enter text.

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

☐ Independent Laboratory

☐ Physician's Office Laboratory

☐ Hospital Inpatient Laboratory

☐ Other

If Other, please specify
Click here to enter text.

24. For each proposed coding change, please provide (attach) a clinical vignette that describes the typical patient who would receive the procedure(s)/service(s) including diagnoses and relevant conditions. Please refer to the sample format and examples of appropriate clinical vignettes included in the code change application instructions. This same vignette may be used during the development of work values by the AMA/Specialty Society RVS Update Committee (RUC), as appropriate. It is important that the description of the typical patient make apparent the degree of complexity required to provide the service. (A vignette is not required when submitting solely for the Administrative MAAA code set).

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25. For each proposed coding change, please provide (attach) a brief description of the procedure(s)/service(s) performed, including those performed by the qualified health care professional (QHCP), as appropriate. When including services performed by a QHCP, this should be a summary description and should **not** contain the detail of pre-, intra- and post-service breakdowns that are required as part of the AMA/Specialty Society RVS Update Committee (RUC). It is important that the description of the service make apparent the degree of complexity required to provide the service. Please refer to the sample format and examples of appropriate descriptions of service included in the code change application instructions. If the description includes services that are reported separately, please clearly indicate this separate reporting

Click here to enter text.

26. Please forward the following documentation with your application, if appropriate. (This step is not required if submitting solely for the Administrative MAAA code set.) If not otherwise appropriate, please indicate why.

a). A copy of the manufacturer's product insert that accompanies the test(s). Accompanying file name

Click here to enter text.

b). A copy of a standard CLSI format procedure from a licensed, accredited, or certified clinical laboratory that currently employs the test. Accompanying file name:

Click here to enter text.

c). Positive, negative and equivocal (if applicable) redacted (i.e., personal health information removed) sample clinical reports of the tests. Accompanying file name:

Click here to enter text.

d). Up to three articles (preferable United States peer-reviewed literature) that describe the test and test performance, including its clinical utility. Do not include references that describe the underlying disease or diagnostic condition for which the test is ordered or studies that only establish that a particular gene or molecular analyte can be measured.

Click here to enter text.

Reference Material

1. Reference Title:
   Click here to enter text.

   Accompanying file name:
   Click here to enter text.

   Summary of the reason that this reference was provided:
   Click here to enter text.

2. Reference Title:
   Click here to enter text.

   Accompanying file name:
   Click here to enter text.

   Summary of the reason that this reference was provided:
   Click here to enter text.

3. Reference Title:
   Click here to enter text.

   Accompanying file name:
   Click here to enter text.

   Summary of the reason that this reference was provided:
   Click here to enter text.

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	

American Medical Association
CPT Coding, Editorial and Regulatory Services
AMA Plaza
330 N. Wabash Avenue, Suite 39300
Chicago, IL 60611-5885
Phone (312) 464-5486
Fax (312) 224-6916

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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Voice (312) 464-5486, fax (312) 224-6916