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| 11-0258 AMA electronic-chgo_lh | Coding Change ApplicationMolecular Pathology Multianalyte Assays Algorithmic Analyses-Genomic Sequencing ProceduresAmerican Medical Association, Current Procedural Terminology (CPT®) |

**Application Submission Requirements**

All CPT code change applications are reviewed and evaluated by CPT 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 CPT staff and/or Editorial Panel members for clarification and information; and
* Compliance with [CPT Lobbying Statement](https://www.ama-assn.org/practice-management/statement-lobbying). (press “Ctrl” key and click link)

**Application Review Links** (Press “Ctrl” key and click link)

* [Applicant’s Name](#applicant)
* [Question 1](#question1)
* [Descriptor](#ballot_question)
* [Typical Patient Description](#vignette)

**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)

Thisform 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.](#general_criteria) (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](#instructions) 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**

1. **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. 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 > 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 > 10% of variants 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 >/=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.

1. **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:

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

[return](#return1)

**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.

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| 11-0258 AMA electronic-chgo_lh |  |
| *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 Lobbying Policy. 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

Individuals or organizations that believe they may be affected by a decision of the CPT Editorial Panel on your code change application may request review of your application in advance of the CPT Editorial Panel meeting. To ensure transparency in the CPT Editorial Panel process, if the AMA receives a request from an interested party (provided they can demonstrate a valid interest) to review this code change application, you will be notified of that request and the identity of the interested party. The required fields indicated below (including supporting documentation) will be provided to the interested party for review. Fields not identified below will not be shared with Interested Parties.

* Applicant name and organization
* 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 SubSpecialties that perform the Service
* Clinical Vignette/Description of patient
* Description of Procedure
* Submitted Literature and other supporting documentation

[ ]  **I agree on behalf of myself and the organization.**

CPT Confidentiality Agreement

In consideration of permission granted to me to participate in the Current Procedural Terminology (CPT®) Code Development Process, including participation on the CPT Editorial Panel, the CPT Advisory Committee, the Health Care Professionals Advisory Committee, the CPT Assistant Editorial Board, and ad hoc and standing workgroups and committees established by the Editorial Panel, I agree:

* I will maintain as confidential any and all materials and information I obtain in connection with my participation in the CPT® Code Development Process including but not limited to the following, which shall collectively be considered “Confidential Information” and proprietary to the American Medical Association:
	+ CPT Editorial Panel meeting agenda materials;
	+ pre-publication CPT codes, modifiers, text descriptors, cross references, and guideline language;
	+ content scheduled for publication in CPT Assistant or other AMA coding products; and
	+ any non-public information disclosed or discussed as part of the CPT Code Development Process, including the content of code change applications and discussions about or evaluations of code change applications by the CPT Editorial Panel, CPT/HCPAC Advisors, and CPT workgroups and committees.

Information shall be considered Confidential Information no matter what format it is provided to or obtained by me including but not limited to verbally, electronically or in print media.

* I will use Confidential Information only in connection with my participation in the CPT Code Development Process. I will not disclose, distribute or publish Confidential Information to any party in any manner whatsoever without the prior written consent of the AMA; however, CPT and HCPAC Advisors, designated representatives of specialty societies, including their designated consultants and lawyers may disseminate Confidential Information to their sponsoring organization for internal use within the organization, and only in connection with providing assistance to the organization and/or its Advisor in evaluating CPT code change applications. I specifically acknowledge that I will not publish or authorize anyone else to publish Confidential Information in any Web posting, article, newsletter, press report and release, publication, or any other communication.
* I will not use any audio or video recording or photographic device in any manner to record or to copy any Confidential Information, including the meetings and proceedings of the CPT Editorial Panel. 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 Agreement.
* I will provide written and/or verbal disclosures as required prior to addressing any agenda item or issue as to which I, or an immediate family member, has a disclosable interest.
* The CPT Editorial Panel can modify or eliminate a code or the language or guidelines associated with a code at any time up to the date of publication of the CPT code set. CPT Editorial Panel actions are not final until publication of the CPT code set. I acknowledge that the early release of Confidential Information, including CPT Editorial Panel actions and any related information, can cause significant problems for physicians, patients, payers and third parties and could cause irreparable injury to the American Medical Association and others.
* Violators of this Agreement may be barred from participation in the CPT Code Development Process.

### [ ]  **I acknowledge and agree on behalf of myself and the organization.**

Copyright Assignment

All copyright in and to any works such as codes, descriptions, guidelines, and parentheticals, 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 copyright and I hereby assign to the AMA any right, title and interest in and to such copyrightable works on behalf of myself and the organization named below.

### [ ]  **I acknowledge and agree on behalf of myself and the organization.**

**Statement of Compliance with the CPT Conflict of Interest Policy**

**For convenience, key elements of the Conflict of Interest Policy applicable for Presenters are summarized below. The Conflict of Interest Policy in its entirety is controlling (please refer to the** [**Conflict of Interest Policy**](https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/cpt/cpt-conflict-of-interest-june-2017.pdf) **in its entirety):**

**Every applicant for a code change application or their designee(s) making a presentation (“Presenter”) to the CPT Editorial Panel on a code change application shall disclose all individual and corporate disclosable interests held by the Presenter, or immediate family member, but without regard to financial limit. Verbal disclosures are required prior to addressing the Panel about any agenda item or issue as to which the Presenter, or immediate family member, has a disclosable interest. Any disclosable interest that is a material individual interest or a material corporate interest (“material” means a disclosable individual or corporate interest that exceeds $10,000 USD in the aggregate within the past two years and in the case of corporate interests, is reasonably expected to exceed $10,000 in the next two years) must be designated as such in the disclosure by checking the box next to the disclosable interest identified below.**

**NOTE: Disclosures of interests does not include [i] any interest that is limited to providing clinical services to patients (including the service for which a code change application has been submitted), or [ii] providing professional educational services or interpretative advice on proper coding.**

**If no disclosable interests, type and enter “NONE.”**

**DISCLOSABLE INTERESTS (INDICATE IF MATERIAL)**

[ ]

[ ] I affirm that I have read and understand the [**Conflict of Interest Policy**](https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/cpt/cpt-conflict-of-interest-june-2017.pdf). I have no individual or corporate disclosable interests at this time, except as disclosed above. I understand that I have a continuing obligation to comply with the CPT Conflict of Interest Policy and will update this form, as needed, prior to submission or discussion of any code change application. Disclosure does not restrict or limit the ability of the presenter to support the applicant’s code change application.

**Attestations**

I hereby attest to each of the following:

1. I understand that my code change request will be evaluated by the CPT Editorial Panel, CPT/HCPAC Advisors, Members of Advisory Committees, as applicable, and CPT staff. I will cooperate with requests from the CPT Editorial Panel, CPT/HCPAC Advisors, committee members and CPT 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](https://www.ama-assn.org/practice-management/statement-lobbying).
3. I understand that this application is not complete until I and the other co-applicants (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 signed application or the requested documentation within the requested timeframe will prevent CPT staff from processing my code change request. If the code change request is not submitted in time for the upcoming Panel meeting, I will need to resubmit an application for consideration by the Panel at a later date.
4. I understand that after I submit this code change request, 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 discussion falls under the authority of the Editorial Panel, and the application may not be withdrawn.

### [ ]  **I acknowledge and agree on behalf of myself and the organization.**

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](http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes/request-form-pathology-laboratory.page). 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](http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes/request-form-instructions.page). For other forms, see the [AMA CPT website](http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes.page).

(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](http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes/request-form-instructions.page) 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](#Submittinginstructions) 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 discussion falls under the authority of the Editorial Panel, and the application 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.**

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| **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 from the Food and Drug Administration (FDA)? (not a strict requirement for code assignment)

[ ]  Yes (Go to Question 2)

[ ]  No (Go to Question 3)

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

[ ]  Yes

[ ]  No

1. 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.

1. 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.

1. Following the [Code Descriptor Formatting Instructions](#code), 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](https://www.ama-assn.org/practice-management/cpt%C2%AE-coding-change-request-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).

**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.

1. 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.

1. 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.

1. 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.

1. 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.

1. 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.

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

Click here to enter text.

1. 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.

1. 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

1. 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

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

Click here to enter text.

1. 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.

1. 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.

1. 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

1. 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

1. 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.

1. 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.

1. 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.

1. 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.

1. 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).

Click here to enter text.

1. 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.

1. 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.

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.

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.

**Other Comments**:

Click here to enter text.

**Final Attestations**

|  |
| --- |
| By signing below, I 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;
 |
| 1. 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](http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes.page) (press “Ctrl” key and click link) page and on related pages; and
 |
| 1. I have authority to sign this application in both an individual and organizational capacity.
 |

|  |  |
| --- | --- |
| Signature |  |
| Print Name |  |
| Organization (if applicable) |  |
| Date |  |

|  |  |
| --- | --- |
| 11-0258 AMA electronic-chgo_lh | American Medical AssociationCPT Coding, Editorial and Regulatory ServicesAMA Plaza330 N. Wabash Avenue, Suite 39300Chicago, IL 60611-5885Phone (312) 464-5486Fax (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.

**AMA CPT Editorial Research and Development**

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

**Instructions for** **Submitting your Code Change Application**

**Coding Change Application:**

* Email the application and any signature pages to **ccpsubmit@ama-assn.org**.
* **Only the Coding Change Application and any signature pages should be emailed to** **ccpsubmit@ama-assn.org****.**

**Supporting documents** for your code change application should be uploaded to the [AMA CPT Submissions](https://connection.ama-assn.org/sites/CPT/Submit/default.aspx) page (<https://connection.ama-assn.org/sites/CPT/Submit/default.aspx>).

* You will be required to sign in to have access to this site.
* Any AMA website login account that you currently have (including your CPT Collaboration website username and password) should allow access to this site.
* If you do not have an AMA login account, press the link that says **Create an Account** on the login page in order to establish access to the **AMA CPT Submissions site**.

**To use the drag and drop option for submissions of documents:**

* The AMA CPT Submissions site is compatible with the following browsers: Internet Explorer, Chrome and Firefox. We have found that using Mozilla Firefox provides optimum performance. This browser can be obtained with a free download through the [Mozilla website](https://www.mozilla.org/en-US/firefox/).
* **Open the AMA CPT Submissions** site using the link shown above. (Click the AMA CPT Submissions link or copy and paste the URL onto your browser address bar.)
* On the login screen, enter your username and password.
* Open the file on your computer that contains the documents to be uploaded.
* To make things easier, decrease the size of the window that you just opened as well as the size of the AMA CPT Submissions window.  You may do this by clicking the icon that has the "2 overlapping boxes" located in the upper right hand corner of each page.
* **Hold the Ctrl key down** and highlight the files on your computer that you want to upload to the AMA CPT Submissions site.
* Place your curser in this group of highlighted files, hold down the left button on your mouse and drag the documents from the source file directly to the AMA CPT Submissions site just below the heading **Drop Off Library**.
* When you see the notice **Drop Here** on the AMA CPT Submissions site, release the mouse button, and the files will transfer over. You will see the titles to the documents that you just submitted.
* If you decide to **upload each document separately**, press the “New Document” link. An “upload dialog box” will open allowing you to submit an individual document. These documents will not appear on the CPT Submission home page. They will be uploaded directly to the CPT staff site.

For security reasons, the files that you upload or drag and drop to the AMA CPT Submissions page will not be visible by any person other than you.  Within approximately one hour, these items will be transferred to a different site that will allow the CPT Staff to review them.

[return](#return1)