Pathology/Laboratory (Including MoPath/GSP/MAAA)

American Medical Association | Current Procedural Terminology (CPT®)

This Pathology and Laboratory code application requires the following documentation, if appropriate:

1. Information about the test procedure
    a. For FDA-approved or cleared tests:
        1. A copy of the manufacturer's product insert that accompanies the test(s)
        2. FDA Summary of Safety and Effectiveness Data (SSED)
    b. For non-FDA approved or cleared laboratory developed tests (LDTs):
        1. A copy of a standard operating procedure (SOP), written in CLSI or similar from a licensed, accredited, or certified clinical laboratory that currently employs the test.
2. Sample reports of all possible outcomes (negative, positive, etc.), with personal information redacted
3. Published guidelines on clinical usage (eg, National Comprehensive Cancer Network [NCCN] clinical guidelines, GeneReviews®, medical specialty societies), if available

Required Literature:

1. If the test is FDA-approved and served as a Clinical Trial Assay (CTA), then associated publications that relate to the test's clinical validity should be included with the application.

2. At least three, and no more than five, peer-reviewed articles related to the test analyte's clinical validity.
    a. At least one reference should address the disease association of the test.
    b. If the test method has not been previously associated with the analyte(s), then at last one reference should address the analytical performance characteristics of the test method relevant to the specific analyte(s) tested.

You will be asked to upload the corresponding literature.

CPT Code Change Application

Application Submission Requirement

All CPT Code Change applications are reviewed and evaluated by AMA staff, the CPT/HCPAC Advisory Committee, and the CPT Editorial Panel. Applications for laboratory analyses are also reviewed by the Pathology Coding Caucus (PCC)

Applications for the Molecular Pathology, Genomic Sequencing Procedures, and Category I and Administrative Multianalyte Assays with Algorithmic Analyses

subsections of the CPT code set are reviewed by the Molecular Pathology Advisory Group (MPAG) in addition to the aforementioned parties.

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.

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

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.

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).
- The analysis involves ≥ 10 variants identified in unrelated families. Multiple reports of the same variant may be included.
- For duplication/deletion (dup/del) assessment for code assignment, the following guideline will be used:

  ≥ 10% of variants should have been associated with dup/del in a recognized database (eg, GeneReviews®, BIOBASE Human Gene Mutation Database [HGMD®] Professional, ClinVar).

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.

Administrative Multianalyte Assays with Algorithmic Analyses (MAAA)

The minimum standard for inclusion in this list is that an analysis is available for patient care.

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 Section I (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, 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.

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

8. 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.

9. 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.

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 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,** during the course of the year and annually at the request of the Chair of the Editorial Panel**. Disclosure does not restrict or limit the ability of the presenter to support the Applicant's code change application.**

EVERY APPLICANT AND PRESENTER WILL RECEIVE AN EMAIL CONTAINING THE STATEMENT OF COMPLIANCE WITH THE CPT CONFLICT OF INTEREST POLICY FOR COMPLETION USING DOCUSIGN. THE APPLICATION IS NOT COMPLETE UNTIL AMA STAFF RECEIVES EACH STATEMENT OF COMPLIANCE.

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.**

I. Rationale/Code descriptor

I. 1 Rationale for Code Change

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

Enter rationale here

I. 2 Code Placement

If this is a request for a new or revised code, what code placement is being suggested?

Category I Codes:

- ☐ Molecular Pathology
- ☐ GSP or other Molecular Multianalyte Assay
- ☐ Category I MAAA
- ☐ Other Pathology/Laboratory (specify subsection [eg, Chemistry, Microbiology])

☐ Administrative MAAA

☐ Category III

☐ **Molecular Pathology code (must meet Category I code criteria)**

I. 3 Proposed Code Changes

Using the search, editing and preview tools, and following the Code Descriptor Formatting Instructions, specify the proposed new, revised and/or deleted codes, descriptors, inclusionary and exclusionary parentheticals and guidelines (as applicable) to be included in your ballot. Mark not just the individual code changes, but all current codes related to your request that you include that haven't been modified. For content you include that hasn't been modified, use the **For Placement Only** (flag icon) tool to indicate no change has been made and it is for reference only (Refer to the code change application instructions for more detailed information.)

Please consider, to the degree possible, what other section of CPT might be affected when making changes in a particular area and list the complete family of codes related to your request (Click here for additional information regarding code change application instructions).

Create New Code Identifier

New Code Changes:

When requesting a new code, enter a temporary five-alphanumeric in the "Enter New Code" box below. After entering these five characters, click the "Add" button. Refer to the Code Descriptor Formatting Instructions if necessary.

- If you are requesting a Category I application, your temporary code should include an "X" in the third digit of the code, e.g., 12X34.
- If you are requesting a Category III application, your temporary code should include an "X" in the third digit of the code and a "T" as the last digit, e.g., 04X3T.

- If this is a request for a new, revised, or deleted code, specify the recommended terminology (code descriptor) for the proposed code. If proposing a Molecular Pathology, GSP, Category I MAAA, or Administrative MAAA code, please use standardized nomenclature for these code sets. Genes should be represented using HUGO-approved gene names and abbreviations. Include gene variants as applicable.
- Specify the placement of the proposed code (e.g., Multianalyte Assays with Algorithmic Analyses, Hematology and Coagulation, etc.). Also list synonyms or other technical names that may be used for the test or testing procedure (e.g., ●8717X Pinworm exam (eg, cellophane tape prep).

Enter proposed language here

II. Data collection

II. 1 Tests Performed Annually

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

< 50

50 – 99

100 – 499

500 – 999

1,000 – 9,999

10,000 – 99,999

> 100,000

Explain:

II. 2 Tests performed in Laboratories

Is this test(s) you are proposing performed by multiple laboratories (e.g. reference laboratories, hospital laboratories, physician office laboratories)?

Yes

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

<5

5 – 10

11 – 20

21 – 49

50 – 99

100 – 499

500 – 999

1,000 – 9,999

10,000 – 99,999

> 100,000

○ No

Do you anticipate this number to change in the future? If yes, why (NOTE: anticipated volume increase in itself is an insufficient reason to support issuance of a new CPT code. However, sound, evolving clinical practices will be considered by the CPT Editorial Panel)?

Rationale for anticipated change in number of laboratories performing the test: State Rationale Here. If a change is not anticipated, enter N/A.

II. 3 Distinct Service

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

○ Yes

○ No

Explain:

II. 4 Current Code Justification

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.

Search for Code

Rationale: State Rationale Here. If this is a request for a deleted code, enter N/A.

II. 5 Present Codes Inadequate

Why is (are) the present codes (noted in question II.4) inadequate to describe the test?

If a test represents a variation in a testing methodology or a new analyte employing an existing methodology, do the existing codes describe the test but not to the same level of specificity?

How will specificity created by this code change improve reporting and test identification?

II. 6 Major Code Differences

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 (eg, testing methodologies, associated diseases).

Search for Code

Differences: State Differences Here. If there are no differences, enter N/A.

II. 7 Integral Codes

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

Integral Codes: List codes here. Type none if not applicable.

II. 8 Performance or Quality Measure by any National Organization

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

Yes

Organization:

Measure Name:

- No
- Don't Know

II. 9 Diagnosis/Condition for Treatment

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

Diagnoses, symptoms and/or conditions: Enter N/A if not applicable.

II. 10 Prevalence of Diagnoses

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

II. 11 Analyte/Biomarker-Disease Association

Has the analyte/biomarker-disease association been established? If yes, please provide up to three relevant citations.

- Yes

File Uploader:

Drag and Drop Files Here:

- No

Add a radial for same as above option

II. 12 Years of Procedure Being Performed

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

Duration in Years

Select Duration

<1

2

3

4

5

6

7

8

9

10

>10

Source: Cite source here. If there is no source, enter No source.

II. 13 Clinical Laboratory Improvement Amendment

How is this test classified under CLIA?

- high complexity
- moderate complexity
- waived

II. 14 Estimated Percentage Usage

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

Now Reported As

Enter Codes Here. If there are no codes, enter N/A.

Percentage

Enter Percentage

II. 15 Practice Guidelines

Are you aware of any published guidelines regarding clinical usage of this test (eg, National Comprehensive Cancer Network [NCCN] clinical guidelines, GeneReviews®, medical specialty society policy statements)? If yes, please provide copies.

- Yes

File Uploader:

Drag and Drop Files Here:

- No
- Don't Know

II. 16 Proprietary Test Interest (for Category I and Administrative MAAA tests only)

Are you a proprietor, manufacturer, or performing laboratory?

- Yes
- No

Identify other stakeholders who have an interest in this test.

Other stakeholders who have an interest in the test:

Name(s):

Address(es):

Email address(s):

II. 17 Contacting Laboratory

Have you contacted the relevant stakeholders (i.e. performing laboratory(ies) and test proprietor) of the procedure represented in this proposal (answer required only if requesting a Category I MAAA code or Administrative MAAA code)?

- Yes

If yes, please describe the interaction and disclose whether or not the stakeholder(s) supports the code change request:

- No
- N/A

III. Physician Services

III. 1 Performing Specialties

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

Search for Specialty

Select Specialty

III. 2 Site of Service

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

- ☐ **Independent Laboratory**
- ☐ **Physician's Office Laboratory**
- ☐ **Hospital Laboratory**
- ☐ **Emergency Medical Transport Facility**
- ☐ **Home Health Service Laboratory**
- ☐ **Other**

IV. Vignette-typical patient/description of procedure

IV. 1 Clinical Vignette/Typical Patient

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

Clinical Vignette: Enter Clinical Vignette here. Do not exceed 75 words. If this is a request for a deleted code, enter N/A.

IV. 2 Description of Procedure

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

Description: Enter Description of Procedure here. If this is a request for a deleted code, enter N/A.

V. Supporting Documentation

V. 1 Copy of Manufacturer's Product Insert

This step is only required for applications for FDA-approved for cleared tests. Please forward the following documentation with your application, if appropriate. If not appropriate, please indicate why.

A copy of the manufacturer's product insert that accompanies the test(s)

- Yes

File Uploader:

Drag and Drop Files Here:

- No

Please indicate why:

V. 2 FDA Summary of Safety and Effectiveness (SSED)

This step is only required for applications for FDA-approved or cleared tests. Please forward the following documentation with your application, if appropriate. If not appropriate, please indicate why.

A copy of the FDA SSED

- Yes

File Uploader:

Drag and Drop Files Here:

- No

Please indicate why:

V. 3 Standard Operating Procedure (SOP)

This step is only required for applications for laboratory-developed tests (LDTs) that are not FDA approved. Please forward the following documentation with your application, if appropriate.

A copy of an SOP written in CLSI or similar format from a licensed, accredited, or certified clinical laboratory currently performing the test. The SOP must include sufficient

technical detail to support development of an appropriate CPT code descriptor for the test.

- Yes

File Uploader:

Drag and Drop Files Here:

V. 4 Intended Use, Principle, Limitations

If not addressed in the SOP submitted for this test, please answer the following questions. If the requested information is addressed in the SOP, please enter "Addressed in SOP":

1. Describe the intended use of the test:

Describe here

2. Describe the principle behind the test:

Describe here

3. Are there any test limitations?

Describe here

V. 5 Sample Clinical Reports

Please forward the following documentation with your application, if appropriate. If not appropriate, please indicate why.

Redacted (ie, personal information) sample clinical reports of all possible outcomes of the test(s) (eg, positive, negative, etc.).

- Yes

File Uploader:

Drag and Drop Files Here:

- No

Why?

- N/A

V. 6 U.S. versus Foreign Population

Was the study(ies) submitted with your application performed on foreign populations? If yes, are the results of the study(ies) applicable to populations in the U.S. population? If yes, please provide documentation to substantiate that the results of the study(ies) are relevant to the U.S. population.

- Yes

File Uploader:

Drag and Drop Files Here:

- No

V. 7 Reference Citations

The literature requirements set forth below define the minimum requirements for CPT Editorial Panel ("Panel") consideration of the application. The Panel members review the literature provided and each member makes an independent evaluation of whether the literature submitted with the application satisfies the criteria for a code change. Applicants are urged to submit the strongest literature that supports the application. IMPORTANT: Meeting the minimum literature requirements does not guarantee that the Panel will determine clinical efficacy of the procedure or service has been adequately demonstrated in the submitted literature. The merit of the application is based on the totality of the information in the application and other relevant information brought to the attention of the Panel. The literature requirements apply to applications that seek addition of a new procedure/service, or a new use for an existing code(s). Applicants who seek an editorial change (i.e., application seeks only editorial revision of the existing code or a clarification of use), with no change to the intended use of the code or related instructions are not obligated to meet the literature requirements. The Panel members will review suggested revision and each member makes an independent evaluation of whether the request satisfies the criteria for "editorial change only" applications.

Please provide electronic (PDF or Word documents) copy(ies) (and internet addresses, if available) of literature to support your application:

1. Provide a concise "relevance statement".
2. If the test is FDA-approved and served as a Clinical Trial Assay (CTA), then any associated publications that attest to the test's clinical validity and utility should be included with the application.
3. At least three, and no more than five peer-reviewed articles related to the test analyte's clinical validity and utility. At least one reference should address the disease association of the test. Do not include references that describe the underlying disease or diagnostic condition for which the test is ordered. Different authors are preferred (i.e., no overlapping authors with the same patient population among the articles submitted). Articles submitted with the designation of "Confidential" will not be accepted nor included in the supporting literature reviewed by the CPT Editorial Panel. Abstracts, book chapters, white papers, advertising

material, instructional manuals, and non-peer reviewed publications are not allowed to accompany application submissions and will not be accepted as substitutes for full-length journal articles. Any "in press" manuscripts that are submitted will only be appropriate for consideration by the Panel if accompanied by the letter from the editor/publisher of the applicable journal informing the author that the manuscript has been accepted for publication in its final form, subject only to final copy editing. It is the responsibility of the submitter to ensure that such submission to the CPT Editorial Panel (despite its very limited use by the Editorial Panel) does not jeopardize publication of the article being considered and such text be available for Panel use.

4. Well-designed studies submitted for consideration should represent the most informative and compelling peer-reviewed publications that directly support the application. Therefore, it is assumed that the requestors are endorsing studies that are well-designed and executed, ethical in nature, and directly supports the code change request. Foreign and mixed (i.e., U.S. & foreign) studies submitted to meet the literature requirements will be judged by the same criteria as U.S. based studies.
5. If this request is an "Editorial Only" change, or has been referred by the RUC for editorial change by the CPT Editorial Panel and has been reviewed and approved through the CPT/RUC process within the last 5 (five) years, the requestors may choose not to submit literature. However, the referral letter from RUC or CMS should accompany the submission for full explanation. If the Editorial Panel determines that supporting literature is required for the editorial change application, then this application will not be considered by the full Editorial Panel until the necessary literature is submitted.

General guidelines for article inclusion and literature requirements

Below you will be asked to upload the corresponding literature for each code requested.

(You will be able to include additional citations once you have completed the file upload)

Publication Details and Attributes

Based on the literature requirements detailed above, please select the code to which your particular citation entry applies. Be sure that each of the CPT Codes listed has the appropriate citations detailed and artifacts attached.

This citation is in support of which code(s)?

Copy/Paste Publication Title, Author(s) Name(s), and Year of Publication here

For the citation you referenced above, please upload an electronic (PDF or Word documents) copy(s) of the literature to support your application.

File Uploader:

Drag and Drop Files Here:

For the citation you referenced and uploaded above, please select the level of evidence that describes it:

Level of Evidence

Select LOE

- ○ Ia – Systematic review of RCT
- ○ Ib – Individual RCT
- ○ IIa – Systematic review of cohort studies
- ○ IIb – Individual cohort study
- ○ IIIa – Systematic review of case control studies
- ○ IIIb – Case control study
- ○ IV – Case series
- ○ V – Expert opinion

Level of Evidence Table – LOE

Level	Short Description (based on Oxford Centre 2009)
Ia	Evidence obtained from systematic review of randomized controlled trials
Ib	Evidence obtained from an individual randomized controlled trial ***Randomized Controlled Trial(s):*** *An epidemiological experiment in which subjects in a population are randomly allocated into groups, usually called study and control groups, to receive or not receive an experimental preventive or therapeutic procedure, maneuver, or intervention. The results are assessed by rigorous comparison of rates of disease, death, recovery, or other appropriate outcome in the study and control groups.*
IIa	Evidence obtained from systematic review of cohort studies
IIb	Evidence obtained from an individual cohort study ***Cohort study(ies):*** *The analytic method of epidemiologic study in which subsets of a defined population can be identified who are, have been, or in the future may be exposed or not exposed, or exposed in different degrees, to a factor or factors hypothesized to influence the probability of occurrence of a given disease or other outcome. The main feature of cohort study is observation of large numbers over a long period (commonly years) with comparison of incidence rates in groups that differ in exposure levels.*
IIIa	Evidence obtained from systematic review of case control studies

Level of Evidence Table – LOE

Level	Short Description (based on Oxford Centre 2009)
IIIb	Evidence obtained from a case control study Case-control study(ies): The observational epidemiologic study of persons with the disease (or other outcome variable) of interest and a suitable control (comparison, reference) group of persons without the disease. The relationship of an attribute to the disease is examined by comparing the diseased and non-diseased with regard to how frequently the attribute is present or, if quantitative, the levels of the attribute, in each of the groups.
IV	Evidence obtained from case series Case-series: A group or series of case reports involving patients who were given similar treatment. Reports of case series usually contain detailed information about the individual patients. This includes demographic information (for example, age, gender, ethnic origin) and information on diagnosis, treatment, response to treatment, and follow-up after treatment.
V	Evidence obtained from expert opinion without explicit critical appraisal

Organization Sponsoring Journal

Enter sponsoring journal name here

Total Patients Studied

Enter a number

Relevance Statement

Enter relevance statement here.

V. 8 Conflicting Reference Citations

Have you found any publications, in addition to those cited in the Code Change Application, which offer conflicting data or different opinions, and that you feel are important for Editorial Panel consideration in evaluating this code change application? If so, please provide the literature reference, level of evidence and reason that you consider the publication(s) relevant, and why you excluded them from the articles cited in Reference Citations (V. 7).

Please provide electronic (PDF or Word documents) copy(s) (and internet addresses, if available) of literature to support your application, and cite the author, title, journal, year, volume and page(s) below.

Copy / Paste ONE Citation Here

For the citation you referenced above, please upload an electronic (PDF or Word documents) copy(s) of the literature to support your application.

File Uploader:

Drag and Drop Files Here:

VI. Other Comments

VI. 1 Other Comments

CONFIRMATION

By submitting this code change application, I confirm that the information provided in this application is true, correct and complete, and to the best of my knowledge, accurately depicts current clinical and surgical practice. I also confirm that I have authority to sign this application in both an individual and organizational capacity.

☐ **I, the Applicant, agree.**

Once the application is submitted, no further edits can be made on the application.