



Coding Change Application

Category I CPT Code(s)
Category III CPT Code(s) – Emerging Technology
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](#)

General Criteria for Category I and Category III Codes

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

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

Category Specific Requirements

A. Category I Criteria

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

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

B. Category III Criteria

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

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

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

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

There is:

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



Cover Sheet for CPT® Coding Change Application

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

Date:

Change Requested by:

Name(s):

Organization:

Address:

City: <input type="text"/>	State: <input type="text"/>	Zip Code: <input type="text"/>
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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 procedure/service involve the use of a drug, vaccine product* or device that requires approval or clearance from the Food and Drug Administration (FDA)?

Yes

Device (Go to question 2)

Drug (Go to question 2)

Vaccine Product*

No (Skip to question 5)

* Applications requesting establishment of CPT Codes for vaccine products will not be considered until evidence substantiating completion of Phase III Clinical Trials and review of unblinded data is submitted to AMA. However, coding applications may be considered prior to submission of the Biologic License Application (BLA) to the FDA.

The CPT Editorial Panel, in recognition of the public health interest in vaccine products, may publish new or revised vaccine product codes prior to approval by the US Food and Drug Administration (FDA). These new or revised vaccine product codes will be released in accordance with the semi-annual schedule with the FDA approval pending symbol (↗).

Applications for establishment of new or revised vaccine product CPT code(s) prior to approval by the FDA require submission of the following:

- Evidence that Phase III Clinical Trials have been completed and submitted to the FDA (e.g., letters submitted or received from FDA documenting completion of Phase III study);
- Summary/synopsis of the final results of Phase III studies and unblinded data to substantiate the safety and efficacy of the vaccine (e.g., executive summary of safety and efficacy data submitted to FDA for licensure) for confidential review. Slide presentations are not considered adequate for these requirements;
- Detailed clinical description of the product and a description of how the vaccine will be supplied (e.g., single-dose, multi-dose), including licensed age indication and dosage amount, along with recommendations for terminology and nomenclature consistent with CPT conventions;
- Information on anticipated Advisory Committee on Immunization Practices (ACIP) US vaccine abbreviation assignment for vaccine product if known.

Exclusively editorial changes (e.g., updated or new ACIP US vaccine abbreviation for a vaccine) do not require submission of coding change application.

2. If approval is necessary, have all devices and drugs necessary for performance of the procedure or service received FDA clearance or approval when such is required for performance of the procedure or service?

Yes (FDA has approved or cleared all necessary aspects of the service.)

No (Some necessary element of the service has not received FDA approval or clearance (Provide details).

N/A

3. Does the procedure/service utilize a humanitarian use device (HUD) as defined by FDA?

Yes (go to question 4)

No (skip to question 5)

N/A

4. Has FDA approval or clearance for humanitarian device exemption (HDE) been received authorizing the marketing of the humanitarian use device?

Yes (Submit documentation of the FDA approval or clearance with the application)

No

N/A

5. Indicate the specific reasons why this code change is necessary (rationale). For example, "This is a new procedure, not described in CPT". Avoid non-rationales. Reasons like "no-code currently available" or "need new code" do not describe the clinical reason for which you are requesting a coding revision.

6. Following the [Code Descriptor Formatting Instructions](#) (press "Ctrl" key and click link) on the page 8 of this application form, specify the proposed new, revised and/or deleted codes, descriptors, inclusionary and exclusionary parentheses and guidelines (as applicable) in the box below. 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.)

7. For each **NEW and/or REVISED** code, indicate which CPT or HCPCS Level II code(s) is currently being used for reporting and specify why each current code is inadequate to describe the new and /or revised procedure/service.

[Click here to enter text.](#)

8. For each **NEW and/or REVISED** code, identify the major differences with other related codes already in CPT.

[Click here to enter text.](#)

9. For each **NEW and/or REVISED** code, please specify who typically provides this service? (check all that apply)

Note: each code may be listed under multiple providers categories

- Physician

List applicable code(s): [Click here to enter text.](#)

- Other qualified health care professional (QHP)

List applicable code(s): [Click here to enter text.](#)

- Clinical, non-billing staff (e.g., registered nurse, imaging technologist, lab technician, behavioral healthcare manager, etc.)

List applicable code(s): [Click here to enter text.](#)

- Computerized algorithm, artificial/augmented intelligence or machine learning, etc.

List applicable code(s): [Click here to enter text.](#)

10. Is this a request for a code for a diagnostic test(s)/service(s)?

- Yes If yes, please attach a copy of all data outputs and reports from the test(s)/service(s) provided for clinician review, as well as a sample of the interpretation of this data output by the physician or other qualified health professional who would be reporting each proposed discrete NEW code service.

- No

11. Has the clinical efficacy of the procedure/service for which you are requesting a code change been documented in literature provided with this application?

Yes

No (If no, then do not submit this application but contact the AMA AMA staff office to discuss why this application should be considered)

12. For each **NEW and/or REVISED** code, please estimate the percentage of times a current code(s) is reported that would now be reported using the proposed new and/or revised code. Example: Current code 12345 will now be reported by 123X1 30% of the time and 123X2 70% of the time.

[Click here to enter text.](#)

13. What is the prevalence of the disease(s) that the service(s) or procedure(s) described by the proposed **NEW** code(s) is/are designed to diagnose/treat? Please quantify when possible (e.g., patients per year; admissions per year).

[Click here to enter text.](#)

14. Provide a list of CPT codes which are an integral (inherent) part of the proposed **NEW and/or REVISED** code(s). This list should include all CPT codes that would represent unbundling if reported in addition to the proposed new and/or revised codes.

[Click here to enter text.](#)

15. Will the proposed **NEW and/or REVISED** code(s) typically (more than 50% of the time) be reported on the same date with other CPT code(s)? Or will any current CPT code(s) be reported typically (more than 50% of the time) with the proposed **NEW and/or REVISED** code(s)?

No **Please indicate what percent of time this code is not reported with other services.**

[Click here to enter text.](#)

Yes

Please specify below why the procedure(s)/service(s) are reported using multiple codes instead of just one code (Check all that apply).

The code is an add-on code or a base code expected to be reported with an add-on code.

- Different providers work together to accomplish the procedure/service; each provider reports his/her part of the work using different codes.
- Multiple codes allow flexibility to describe exactly what components of the procedure/service have been performed. **Please indicate what percent of time this code is not reported with other services.**

Click here to enter text.

- Multiple codes are used to maintain consistency with similar codes. **Please indicate what percent of time this code is not reported with other services.**

Click here to enter text.

- Historical precedents.
- Other. Please explain.

Click here to enter text.

16. CPT does not set a global period. However, to assist the CPT Editorial Panel in consideration of the extent of total work involved in each proposed **NEW** code, select a recommended global period. **NOTE:** Information provided on this application has no binding effect on the Centers for Medicare and Medicaid Services and other payers in assignment of global periods.

- 000 (0 days of post procedure work included)
- 010 (10 days of post procedure work included)
- 090 (90 days of post procedure work included)
- ZZZ (add-on code)

When checking ZZZ, the following will need to be provided:

1. Place the following phrase at the end of the add-on code descriptor(List separately in addition to code for primary procedure)”;
2. Add a parenthetical instruction for the code/list of codes with which this/these add-on code/codes can ONLY be reported [(Use [new code 1X1X0] in conjunction with [1X1X1, 1X1X2, 1X1X1]); and
3. Your Typical Patient and Description of Service examples in questions 23 and 24 will follow the format below:

Typical Patient:

During [insert primary procedure name], a [insert age-year-old-sex of patient] who has just [(select one of each) (undergone/received) (surgery/ treatment)] also requires additional [(select one) (surgery/ treatment)] and [(select one) undergoes/receives/is treated with].

Note: This is an add-on service. Only consider the additional work related to [insert description of additional surgery/treatment cited above].

Description of Service:

Following [insert primary procedure name], additional service description here.

XXX (global period does not apply)

What is the rationale for this global period recommendation? (e.g., Is this the same global period as similar codes? Will the proposed procedure(s)/service(s) require related post-service inpatient and or outpatient follow-up visits?)

[Click here to enter text.](#)

17. For each proposed **NEW** code that may have a global period of 000, 010 or 090, do you request the code be modifier 51 exempt (i.e., added to Appendix E)?

Yes

No

18. What is the typical site of service for each proposed **NEW** code(s)? (check all that apply)

Hospital inpatient

Skilled nursing facility

Hospital outpatient

Nursing facility

Ambulatory surgical center

Assisted living facility

Emergency department

Patient's home

Office

Independent laboratory

Inpatient Psychiatric Facility

Other, specify below.

[Click here to enter text.](#)

19. Indicate the diagnoses (ICD codes) or conditions that the service(s) or procedure(s) described by the proposed **NEW** code(s) are designed to diagnose/treat.

[Click here to enter text.](#)

20. For how many years has the service(s) or procedure(s) described by the proposed **NEW** or **REVISED** code(s) been provided for patients? Indicate your source.

[Click here to enter text.](#)

21. Please identify the specialties or subspecialties that might perform the service(s) or procedure(s) described by the proposed **NEW** code(s).

[Click here to enter text.](#)

22. Are the service(s) or procedure(s) described by the proposed **NEW** code(s) performed widely across the United States?

- Yes Please provide the source(s) for all volume, frequency and distribution statements (e.g., published epidemiology, registries, sales statistics).

[Click here to enter text.](#)

- No Only at limited centers/locations. Please explain below.

[Click here to enter text.](#)

23. Do many physicians and/or other qualified health care professionals provide the service(s) or procedure(s) described by the proposed **NEW** code(s)?

- Yes Please provide the source(s) for all volume, frequency and distribution statements (e.g., published epidemiology, registries, sales statistics).

[Click here to enter text.](#)

- No Please explain below.

[Click here to enter text.](#)

24. How often do individual physicians and/or other qualified health care professionals personally perform the service(s) or procedure(s) described by the proposed **NEW** code(s) in a 12 month period?

- Commonly
- Sometimes
- Rarely

25. How often was the service(s) or procedure(s) for each proposed **NEW** code provided nationally in the most recent one-year period?

[Click here to enter text.](#)

26. Are you aware of any practice parameters/guidelines or policy statements about the service(s) or procedure(s) described by the proposed **NEW** code(s)?

- Yes Please specify below.

[Click here to enter text.](#)

- No
- Don't Know

27. For each proposed **NEW and/or REVISED** code(s), provide a clinical vignette that describes the typical patient who would receive the procedure/service including diagnosis and relevant conditions. Please refer to the sample format and examples of appropriate clinical vignettes included in the code change application instructions. NOTE: This same vignette will be used during the development of work relative value units (RVUs) by the AMA/Specialty Society RVS Update Committee (RUC), if the service requires RUC review. It is important that the description of the typical patient make apparent the typical degree of complexity of the patient receiving this procedure/service.

[Click here to enter text.](#)

28. For each proposed **NEW and/or REVISED** code(s), provide a brief description of the procedure/service performed by the physician or other qualified health care professional. Please refer to the sample format and examples of appropriate descriptions of service included in the code change application instructions. This should be a summary description and should not contain the details for 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 services that are integral or separately reported.

If the description includes services that are reported separately, please clearly indicate this separate reporting. If more than one physician or other qualified health care professional is involved in the provision of the total service, please indicate who does what.

[Click here to enter text.](#)

The literature requirements set forth in Question 30 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 that 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, non-laboratory practice expense only service (procedure/service that does not include physician/QHP work), and/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.

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29. Please provide electronic (PDF or Word documents) copy(ies) (and internet addresses, if available) of literature to support your application, and cite the author, title, journal, year, volume and page(s) in the “[Publication Details and Attributes Grid](#)” (press “Ctrl” key and click link) (PDA grid) that follows. Each item of submitted literature shall be identified in the PDA grid according to each of the following requirements:

1. Identify the Level of Evidence by selecting a level from the LOE table below;
2. Identify whether this is a U.S. based journal or a non-U.S. based journal, and identify whether the population studied is U.S., non-U.S., or both;
3. Identify the number of patients studied (total of all group[s] including controls) and indicate whether the study is a prospective study
4. Provide a concise “relevance statement”.
5. **Provide up to 5 references**, of which at least 1 reports the procedure/service in a U.S. patient population (**see Category I Literature Requirements grid**). Of these, at least 2 articles must report different patient populations in addition to having different authors (no overlapping patient populations and no overlapping authors).

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, 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 CPT (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.

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6. 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.

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7. For applications that request addition of multi-code families, provide 2 to 5 additional references for each requested code for a clinically distinct technique(s)/procedure(s) in these related codes. Time differentiation/additional lesions etc. is not an example of a clinically distinct service. Of these, at least 1 should report the procedure/service in an exclusively U.S. patient population. If such is not provided, then at least one must report the procedure/service in a majority U.S. population and provide the specific number/percentage of patients from a U.S. population to be considered. At least 2 articles must report different patient populations in addition to having different authors (i.e., no overlapping patient populations and no overlapping authors).

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8. 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 to not 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.

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Literature Criteria Definitions:

New Technology:

Individuals or organizations putting forth code change applications will be required to specifically indicate the pathway for FDA approval or clearance.

Services or procedures requiring devices or other technology necessitating the following Food and Drug Administration (FDA) pathways are defined for CPT literature requirements as those involving “new” technology:

1. Premarket Approval (PMA) or Investigational Device Exemption (IDE)
2. Panel Track Submission
3. DeNovo 510(k)

Existing or Non-Contributory Technology:

Services or procedures which are approved or cleared via other FDA requirements (e.g., traditional 510(k)) or those which do not involve technology are defined for CPT literature requirements as those where technology is “existing or non-contributory.” Most CPT code change applications currently fall within this category.

Limited, Specialized or Humanitarian Utilization:

Only very few code change applications are anticipated to be designated by this special status, intended to maintain the integrity of CPT literature requirements, but also recognize that such requirements may be impossible to meet for very unique service or procedures. To qualify for this special status, individuals or organizations submitting code change applications must provide documentation of at least one of the following:

1. Evidence that the device or technology involved has been deemed by the FDA to have met criteria for a “Humanitarian Device Exemption.”
2. Proof that the service or procedure is used primarily for humanitarian reasons or is reserved for unique, small and/or underserved populations is the responsibility of requester. Using this level of proof would make it impossible to conduct research to meet CPT literature requirements for more typical or traditional services or procedures. Examples might include surgical procedures to repair rare congenital heart defects or those required to address other rare conditions. Individuals or organizations seeking this status as part of a code change application would be required to provide compelling evidence to the CPT Editorial Panel that the service or procedure for which they seek a code or codes merits this special designation. The burden of evidence for assignment of this status would fall entirely on the requesting individual or organization, and the decision to assign this very unique status rests entirely on the CPT Editorial Panel.

Please note that submittal of articles meeting the minimum literature requirements specified in this application does not necessarily mean that clinical efficacy has been established as

required by the Category I criteria. Whether clinical efficacy has been established in the literature is a judgment reserved for the CPT Editorial Panel.

The following includes a listing of the utilization and technology types that best describe the procedure that is being requested. General Guidelines for inclusion of the articles should be chosen from one of the four types of procedures as listed in the following:

Category I Literature Requirements	Utilization	Typical	Typical	Limited, Specialized or Humanitarian	Limited, Specialized or Humanitarian
	Technology	New	Existing or Non-Contributory	New	Existing or Non-Contributory
Maximum # of Peer-Reviewed Publications Per Distinct Service(s)/Technique(s):		5	5	5	3-5
For each Additional Distinct Service(s)/Technique(s) within Multi-code Family(ies)		2-5	2-5	2-5	2-5
Minimum # with Exclusively U.S. Patient Populations OR Majority U.S. Population (provide specific number/percentage of patients from U.S. population to be considered within PDA Grid Column 7 titled "US or Foreign Population Studied):		1	1	1	1
Minimum # with No Overlapping Patient Populations and No Overlapping Authors:		2	2	1	1
Minimum Level of Evidence for at least One Article		IIa	IIIa/IIIb	IIIb	IV

Make an "X" in the box for the type of utilization and technology that best fits the procedure/literature being requested.

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

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

- 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.

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): <i>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.</i>
IIa	Evidence obtained from systematic review of cohort studies
IIb	Evidence obtained from an individual cohort study
	Cohort study(ies): <i>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.</i>
IIIa	Evidence obtained from systematic review of case control studies
IIIb	Evidence obtained from a case control study
	Case-control study(ies): <i>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.</i>
IV	Evidence obtained from case series
	Case-series: <i>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.</i>
V	Evidence obtained from expert opinion without explicit critical appraisal

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

Publication Details and Attributes (PDA) Grid
Use the following grid for each distinct service requested.
Applicable Proposed or Existing Code(s) # ____ Click here to enter text.

Article #1	Length of Follow-up	Level of Evidence Based on LOE Table	U.S. or Foreign Peer Reviewed	Organization Sponsoring Journal	Impact Factor	U.S. or Foreign Population Studied (REQUIRED)	Prospective Study?	Total Patients Studied
Publication Title: Author(s) Name(s): Year of Publication:			<input type="checkbox"/> US <input type="checkbox"/> Foreign			<input type="checkbox"/> US <input type="checkbox"/> Foreign <input type="checkbox"/> Both (If answered both: Provide specific % of patients <u>OR</u> # of patients for both regions) Population % U.S. Foreign % ____ % ____ <hr/> Population # U.S. Foreign # ____ # ____	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Provide brief description regarding relevance to code change application*								
Article #2	Length of Follow-up	Level of Evidence Based on LOE Table	U.S. or Foreign Peer Reviewed	Organization Sponsoring Journal	Impact Factor	U.S. or Foreign Population Studied (REQUIRED)	Prospective Study?	Total Patients Studied
Publication Title:			<input type="checkbox"/> US <input type="checkbox"/> Foreign			<input type="checkbox"/> US <input type="checkbox"/> Foreign <input type="checkbox"/> Both	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Author(s) Name(s):						(If answered both: Provide specific % of patients OR # of patients for both regions) Population % U.S. Foreign %____ %____		
Year of Publication:						Population # U.S. Foreign #____ #____		

Provide brief description regarding relevance to code change application*

Article #3	Length of Follow-up	Level of Evidence Based on LOE Table	U.S. or Foreign Peer Reviewed	Organization Sponsoring Journal	Impact Factor	U.S. or Foreign Population Studied (REQUIRED)	Prospective Study?	Total Patients Studied
Publication Title:			<input type="checkbox"/> US <input type="checkbox"/> Foreign			<input type="checkbox"/> US <input type="checkbox"/> Foreign <input type="checkbox"/> Both (If answered both: Provide specific % of patients OR # of patients for both regions) Population % U.S. Foreign %____ %____	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Author(s) Name(s):						Population # U.S. Foreign #____ #____		
Year of Publication:								

Provide brief description regarding relevance to code change application*

Article #4	Length of Follow-up	Level of Evidence Based on LOE Table	U.S. or Foreign Peer Reviewed	Organization Sponsoring Journal	Impact Factor	U.S. or Foreign Population Studied (REQUIRED)	Prospective Study?	Total Patients Studied
Publication Title: Author(s) Name(s): Year of Publication:			<input type="checkbox"/> US <input type="checkbox"/> Foreign			<input type="checkbox"/> US <input type="checkbox"/> Foreign <input type="checkbox"/> Both (If answered both: Provide specific % of patients <u>OR</u> # of patients for both regions) Population % U.S. Foreign % ____ % ____ <hr/> Population # U.S. Foreign # ____ # ____	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Provide brief description regarding relevance to code change application*								
Article #5	Length of Follow-up	Level of Evidence Based on LOE Table	U.S. or Foreign Peer Reviewed	Organization Sponsoring Journal	Impact Factor	U.S. or Foreign Population Studied (REQUIRED)	Prospective Study?	Total Patients Studied
Publication Title: Author(s) Name(s): Year of Publication:			<input type="checkbox"/> US <input type="checkbox"/> Foreign			<input type="checkbox"/> US <input type="checkbox"/> Foreign <input type="checkbox"/> Both (If answered both: Provide specific % of patients <u>OR</u> # of patients for both regions) Population % U.S. Foreign % ____ % ____ <hr/> Population # U.S. Foreign # ____ # ____	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Provide brief description regarding relevance to code change application*

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31. Are there any overlapping authors within the PDA grid above?

- Yes (go to 32.)
- No (skip to 33.)

32. List the names of overlapping authors and the nature of different populations for the overlapping authors

Example of differentiation of listing:

Article #	Author Name:	Population Differences:
1	Christopher Andrews	20 patients from Mayo Clinic
3	Christopher Andrews	17 Patients, Rush Presbyterian/St. Lukes

Article #	Author Name:	Population Differences:

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33. 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 30.

Reference (list Author, Title, Journal, Year, Volume, Pages)	Level of Evidence based on LOE Table	Brief description regarding relevance and why you excluded from articles in 29a.
Article #1	Level #	Describe:
Article #2	Level #	Describe:

Article #3	Level #	Describe:
Article #4	Level #	Describe:

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

AMA CPT Editorial Research and Development

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

For reference only