

American Medical Association Current Procedural Terminology (CPT) Information on Criteria for CPT Development

Guidance from CPT Manual, Instructions for Use of the CPT Codebook:

Select the name of the procedure or service that accurately identifies the service performed. Do not select a CPT code that merely approximates the service provided. If no such specific code exists, then report the service using the appropriate unlisted procedure or service code. In surgery, it may be an operation; in medicine, a diagnostic or therapeutic procedure; in radiology, a radiograph. Other additional procedures performed or pertinent special services are also listed. When necessary, any modifying or extenuating circumstances are added. Any service or procedure should be adequately documented in the medical record.

From AMA Website: Applying for a CPT Code

<http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes.page>

Standards For Providing Guidance Regarding Existing or New CPT Codes

AMA CPT Editorial Panel Criteria

The CRC has voted to follow CPT Editorial Panel Criteria when reviewing requests for coding guidance and/or requests for new/revised/deleted CPT codes. The criteria for Category I and Category III CPT codes are as follows obtained by AMA CPT website:

Criteria for development and evaluation of CPT® Category I and Category III Codes

Application Submission Requirements

All CPT code change applications are reviewed and evaluated by CPT staff, the CPT/HCPAC Advisory Committee, and the CPT Editorial Panel. Strict conformance with the following is required for review of a code change application:

- Submission of a complete application, including all necessary supporting documents;*
- Adherence to all posted deadlines;*
- Cooperation with requests from CPT staff and/or Editorial Panel members for clarification and information; and*
- Compliance with CPT Lobbying Policy.*

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.

From AMA Website CPT Request Form

<http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/applying-cpt-codes/request-form-categories-i-iii.page?>

Literature Requirements to accompany AMA Code Change Proposal (CCP).

The AMA Code Change Proposal requires specific literature criteria to be met to accompany all CCPs. The requirements are outlined in question 25a. on the CCP below:

25a. 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) 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. or non-U.S. or both;
3. Identify the number of patient studies (total of all group(s) including controls) and indicate whether study is a prospective study;
4. Provide a concise “relevance statement”.
5. **Provide up to 5 references**, of which at least 3 report the procedure/service in a U.S. patient population. Of these, at least 2 articles must report different patient populations or have different authors (no overlapping patient populations or no overlapping authors). 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.

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
# of Peer-Reviewed Publications:		5	5	5	3-5
Minimum # with U.S. Patient Populations:		3	3	2	1
Minimum # with Different Patient Populations:		2	2	1	1
Minimum Level of Evidence for at least One Article		IIa	IIIa/IIIb	IIb	IV
Make an "X" in the box for the type of utilization and technology that best fits the procedure/literature being requested.					

25b. 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 practioners 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
IIa	Evidence obtained from systematic review of cohort studies
IIb	Evidence obtained from an individual cohort study
IIIa	Evidence obtained from systematic review of case control studies
IIIb	Evidence obtained from a case control study
IV	Evidence obtained from case series
V	Evidence obtained from expert opinion without explicit critical appraisal