



Category I/III CPT Code Change Application Literature Requirements

American Medical Association | Current Procedural Terminology (CPT®)

The literature requirements set forth below define the minimum requirements for CPT Editorial Panel (“Panel”) consideration of a Category I/III Long Form 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, and cite the author, title, journal, year, volume and page(s) in the “Publication Details and Attributes Grid” (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 (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.

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.
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. 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).
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.

New Technology:	Limited, Specialized or Humanitarian Utilization:
<p>Individuals or organizations putting forth code change applications will be required to specifically indicate the pathway for FDA approval or clearance.</p> <p>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:</p> <ol style="list-style-type: none"> 1. Premarket Approval (PMA) or Investigational Device Exemption (IDE) 2. Panel Track Submission 3. DeNovo 510(k) <p>Existing or Non-Contributory Technology:</p> <p>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</p>	<p>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:</p> <p>Evidence that the device or technology involved has been deemed by the FDA to have met criteria for a “Humanitarian Device Exemption.”</p> <p>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</p>



<p>is “existing or non-contributory.” Most CPT code change applications currently fall within this category.</p>	<p>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.</p> <p>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.</p>
--	--

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 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.				

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 <i>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.</i>
IIa	Evidence obtained from systematic review of cohort studies
IIb	Evidence obtained from an individual cohort study <i>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.</i>
IIIa	Evidence obtained from systematic review of case control studies
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

For more information, visit www.cebm.net/glossary