Pathology/Laboratory (Including MoPath/GSP/MAAA) 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 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.

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
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

Level of Evidence Table – LOE	
Level	**Short Description (based on Oxford Centre 2009)**
	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	