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New LCD Process

The CMS announced in October 2018 the revision of Chapter 13 of Medicare's Program Integrity Manual, which addresses local coverage determination (LCDs). The revisions (the first changes to the manual since 2015) reflect policy process changes in response to legislative requirements and stakeholder comments.

For more information, see the CMS MLN Matters Article at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10901.pdf>.

- Informal Meeting: The new LCD process may begin with informal meetings in which interested parties within the MAC's jurisdiction can discuss potential LCD requests. These educational meetings, which are not required, can be held either in person, using web-based technologies, or via teleconference, which allow discussions before requestors submit a formal request.
- CAC Meetings: MACs must now ensure all CAC meetings are open to the public to attend and observe. These meetings must be recorded and kept on the MAC website and are to be distinguished from the open public/stakeholder meetings.
 - MACs now have the discretion to determine the frequency of the CAC meetings, including whether to have a CAC meeting at all. According to CMS, MACs determine how frequently these meetings occur based on the appropriateness and volume of LCDs requiring CAC input.
 - It appears that many MACs are choosing to hold CAC meetings before the drafting of an LCD as a way of gathering information and obtaining opinions on the evidence being considered.
 - MACs can host CAC meetings in various ways (eg, in-person, telephone, video, webinar).
- LCD Requests: MACs must now consider new LCD requests from a) beneficiaries; b) health care professionals; and c) any interested party doing business in a contractor's jurisdiction. Within 60 days of the day they receive the request, MACs will review the materials and determine whether the request is complete or incomplete. If the request is complete, the MAC will follow the new LCD process, as described in the revised manual.
- Evidentiary Consultation: During an LCD's development, MACs should supplement their research with clinical guidelines, consultation by experts, or medical associations. A summary of opinions received prior to the drafting of a proposed LCD shall be included in the LCD.
- Publication of the Proposed LCD: Once the proposed LCD is published, MACs will provide a minimum of 45 calendar days for public comment. CMS now requires that each MAC summarize the evidence that supports the coverage decision for every proposed and final LCD, including:
 - A description of the item or service under review
 - A narrative that describes the evidence supporting the clinical indications for the item or service
 - The target Medicare population
 - Whether the item or service is intended for use by health care providers or beneficiaries



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- Open Stakeholder Meeting: After the proposed LCD is made public, MACs will hold open meetings to discuss the review of the evidence and the rationale for the proposed LCD(s) with stakeholders in their jurisdiction. Interested parties – including members of the CAC – can make presentations of information related to the proposed LCDs.
- Final Determination and Response to Public Comment: After the close of the comment period and the required meetings and consultation, the final LCD and the Response to Comment Article will be published on the Medicare Coverage Database.
- Reconsideration Requests: Medical professional societies are now specifically mentioned as a stakeholder that can use LCD reconsideration process (though the CAP and other organizations have submitted requests in the past). Within 60 days of the request, a MAC shall determine whether a reconsideration request is valid or invalid. MACs shall also keep an internal list of the LCD reconsideration requests received and the dates, subject, and disposition of each one. If the request is valid, the MAC will open the LCD and follow the process outlined above for new LCDs or include the LCD on the MAC's waiting list.
 - As noted above, CMS kept the requirement that reconsideration requests must include a justification supported by new evidence.
- Relocation of Codes: International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) and Current Procedure Terminology (CPT) codes removed from LCD in the future.

The CMS has indicated that interested stakeholders may submit feedback on their experiences with the revised LCD process via submissions to LCDmanual@cms.hhs.gov and that the agency will consider additional revisions. After CAP leadership discussions with various stakeholders, it appears that MACs may also be gathering feedback and engaging in communications regarding the updated Program Integrity Manual changes.