

Local Coverage Determination Process Summary and Major Provisions

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Summary

The Centers for Medicare and Medicaid Services (CMS) has revised rules for the development and administration of Medicare Local coverage determinations (LCDs), a powerful set of instructions, policies and procedures governing Medicare payment terms applied locally around the country.

CMS' actions centered on changes to [Chapter 13 of the Medicare Program Integrity Manual \(PIM\)](#), where the LCD process is described. LCDs are administrative and educational tools intended to help health care providers submit correct claims for payment. They specify the clinical circumstances when a clinical item or service is considered to be reasonable and necessary for Medicare patients within a specified geographic region. The CMS Manual also guides stakeholder engagement in the LCD process. CMS revised the manual in response to a provision of the 21st Century Cures Act to improve transparency in the LCD process. The update is the first for the manual since August 2015. The implementation date is January 8, 2019.

The manual was reformatted for stakeholders to use a roadmap with a step-by-step description of the LCD process that is accessible to all stakeholders. Such transparency carries through to the reconsideration process. The revisions now enable stakeholders to ask a MAC to take a second look at an existing decision using evidence that has developed since its previous review. And, it also sets forth consistent requirements for provider/stakeholder communications, which now must occur at predictable milestones so anyone with an interest in a LCD's development can stay informed as it moves through the process.

The following exhibits were **deleted** from the revised Medicare Integrity Manual

- Exhibits/3/Description of CAC Members
- Exhibits/3/3.1/Physicians
- Exhibits/3/3.2/Clinical Laboratory Representative
- Exhibits/3/3.3/Beneficiaries
- Exhibits/3/3.4/Other Organizations
- Exhibits/6/LMRP Format
- Exhibits/6/6.1/ Local Coverage Determination (LCD) Format

Major Provisions

Local Coverage Determinations (LCD) Definition & Statutory Authority for LCDs 13.1.2 (New)

An LCD, as defined in §1869(f)(2)(B) of the Social Security Act (SSA), is a determination by a Medicare Administrative Contractor (MAC) respecting whether or not a particular item or service is covered on a contractor-wide basis in accordance with section 1862(a)(1)(A) of the Act.

1869(f)(2)(A) of the SSA outlines the process for Administrative Law Judge (ALJ) and Department of Appeals Board (DAB) review of LCDs. This process is known as the LCD Challenge Process. Procedures related to this challenge process are described in 42 Code of Federal Regulation (CFR) part 426.

§1862(l)(5)(B) of the SSA requires the MACs providing services within the same jurisdiction to consult on all new local coverage determinations within the jurisdiction.

The 2016 21st Century Cures Act included changes to the LCD process, adding language to 1862(l)(5)(D) of the SSA to describe the LCD process. Section 1862(l)(5)(D), of the SSA requires each MAC that develops an LCD to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

- (i) Such determination in its entirety.
- (ii) Where and when the proposed determination was first made public.
- (iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.
- (iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.
- (v) An explanation of the rationale that supports such determination.

13.2 LCD Process (New)

General LCD Process Overview 13.2.1 (New)

This section outlines the processes used for informal meetings prior to the development of an LCD, external requests to develop an LCD, consultations, the proposed determination, public comment, the Contractor Advisory Committee, final determination, and the notice period.

Informal Meetings 13.2.2.1 (New)

The LCD process may begin with informal meetings in which interested parties in the MAC's jurisdiction can informally discuss potential LCD requests. These meetings are **for educational purposes only** and are not pre-decisional negotiations. MACs should publish on their contractor websites how an interested party can contact them to set up an informal meeting. These meetings will assure that all relevant evidence needed for review for coverage is submitted with the request for a formal review.

LCD Requests 13.2.2.2 (New)

The New LCD Request Process is a mechanism by which interested parties within a contractor's jurisdiction can request a new LCD. Contractors consider all new LCD requests from:

- Beneficiaries residing or receiving care in a contractor's jurisdiction;
- Health care professionals doing business in a contractor's jurisdiction; and
- Any interested party doing business in a contractor's jurisdiction.

LCD Request Requirements 13.2.2.3 (New)

Contractors shall consider New LCD Requests to be a complete, formal request if the following are met:

- The request is in writing and can be sent to the MAC via e-mail, facsimile or written letter;
- The request clearly identifies the statutorily-defined Medicare benefit category to which the requestor believes the item or service falls under and provides a rationale justifying the assignment;
- The request shall identify the language that the requestor wants in an LCD;
- The request shall include a justification supported by peer-reviewed evidence. Full copies of published evidence to be considered shall be included and failure to include same invalidates the request;
- The request shall include information that addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service; and
- The request shall include information that fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.

The MAC will review materials received within **60 calendar days upon receipt** and determine whether the request is complete or incomplete. If the request is incomplete, the contractor shall respond, in writing, to the requestor explaining why the request was incomplete. If the request is complete, the MAC shall follow the process outlined in chapter 13 of Pub.100-08.

Clinical Guidelines, Consensus Documents and Consultation 13.2.3 (New)

Prior to drafting and during the development of an LCD, if available the MACs shall supplement their research (see section 13.5.3) with clinical guidelines, consensus documents or consultation by experts (recognized authorities in the field), medical associations or other health care professionals for an advisory opinion, when applicable.

When a MAC consults with an expert, they shall inform and obtain consent from the expert that their opinion may be used, disclosed publicly, and clearly identified as such within the proposed or final LCD. Acceptance by individual health care providers, or even a limited group of health care providers, does not indicate general acceptance of the item or service by the medical community.

Proposed LCD 13.2.4 (New)

All proposed LCDs, with limited exceptions noted below, must follow the LCD process outlined in 13.2 of this manual, consisting of consultation, publication of proposed LCD, open meeting concerning the proposed policy, opportunity for public comment in writing, publication of a final LCD that includes a

response to public comments received and notice to public of new policy **45 days in advance of the effective date**. These processes shall be used for all LCDs except in the following situations:

- Revised LCD Being Issued for Compelling Reasons
- Revised LCD that Makes a Non-Substantive Correction - For example, typographical or grammatical errors that do not substantially change the LCD.
- Revised LCD that Makes a Non-Discretionary Coverage Update - Contractors shall update LCDs to reflect changes in Statutes, Federal regulations, CMS Rulings, NCDs, HCPCS code changes for DME, coverage provisions in interpretive manuals, and payment policies.
- Revise LCD to effectuate an Administrative Law Judge's decision to nullify an existing LCD due to an LCD Challenge.

Proposed Determination & Posting of LCD Summary Sheet 13.2.4.1 (New)

The Proposed LCD is the MACs proposed determination regarding coverage, non-coverage or limited coverage for a particular item or service. The public announcement of the MAC's proposed determination **begins with the date the proposed LCD is published** on the Medicare Coverage Database (MCD).

The LCD Summary Sheet is a document that summarizes contractor actions related to the LCD and includes open meeting and CAC information, if applicable. The LCD Summary Sheet will be posted to the MCD.

Public Comment 13.2.4.2 (New)

Once the proposed LCD is published, MACs shall provide a **minimum of 45 calendar days** for public comment. MACs shall contact CMS Business Function Lead (BFL) if they determine an extension to the comment period is needed.

Contractor Advisory Committee (CAC) 13.2.4.3 (New)

MACs shall establish one CAC per state or have the option of establishing one CAC per jurisdiction or multi-jurisdictional CAC with representation from each state. It is expected that if a MAC chooses to have one CAC per jurisdiction or multi-jurisdictional CAC, the MAC shall endeavor to ensure that each state has a full committee and the opportunity to discuss the quality of evidence used to make a determination.

The purpose of the CAC is to provide a formal mechanism for healthcare professionals to be informed of the evidence used in developing the LCD and promote communications between the MAC and the healthcare community. CAC members should serve in an advisory capacity as representatives of their constituency to review the quality of the evidence used in the development of an LCD. The CAC is advisory in nature, **with the final decision on all issues resting with MACs**.

The CAC is to be composed of healthcare professionals, beneficiary representatives, and representatives of medical organizations. The CAC is used to supplement the MAC's internal expertise and to ensure an unbiased and contemporary consideration of "state of the art" technology and science.

CAC members are valued for their background, education, experience and/or expertise in a wide variety of scientific, clinical, and other related fields. The MAC shall endeavor to ensure each specialty that

serves on the CAC shall have at least one member and a designated alternate approved by the MAC. If the CAC member or alternate cannot attend the CAC meeting, a substitute may attend if the MAC is notified and approved at least 1 week prior to the meeting. Contractors have the option of hosting in-person and/or telephonic/video/on-line conference/etc. meetings. All CAC meetings will be open to the public to attend and observe.

Open Meeting 13.2.4.4 (New)

After the proposed LCD is made public, MACs shall 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 (generally those that would be affected by the LCD, including providers, physicians, vendors, manufacturers, beneficiaries, caregivers, etc.) can make presentations of information related to the proposed LCDs. MACs should provide an email address on their contractor website where all interested parties shall submit their presentation materials. However, all formal comments must be submitted in writing to the MAC. Members of the CAC may also attend these open meetings. MACs shall keep a copy of the number of attendees and make a copy available to CMS BFL and COR upon request. MACs shall record (video, audio or both) the Open Meetings and as part of the LCD record, assure the recording is maintained on their contractor website.

MACs are required to notify the public about the dates, times, and location for the open meeting. MACs have the option of setting up email listservs to announce this information or may use other education methods to inform the public. MACs shall post the planned agenda for the open meeting **a minimum of two weeks prior** to the event on their contractor website and will inform the public that the agenda has been posted.

Final Determination 13.2.5 (New)

After the close of the comment period and the required meetings and consultation, the final LCD and the Response to Comment (RTC) Article shall be published on the MCD.

Response to Public Comments 13.2.5.1 (New)

MACs respond to all comments received during the comment period of the proposed LCD by using the Response to Comment (RTC) article associated with the LCD. The RTC Article is published on the start date of the notice period. The RTC article will remain publicly available indefinitely on the MCD or the MCD Archive.

Notice Period 13.2.6 (New)

The date the final LCD is published on the MCD, marks the beginning of the required notice period of a minimum 45 calendar days before the LCD can take effect. If the MAC would like to extend the notice period, they shall seek approval from CMS BFL. If the contractor does not extend the notice period, the **effective date of the LCD is the 46th calendar day** after the notice period began.

LCD Reconsideration Process 13.3 (Revised)

The LCD reconsideration process is a mechanism by which a beneficiary or stakeholder (including a medical professional society or physician) in the MAC's jurisdiction can request a revision to an LCD. The LCD reconsideration process differs from an initial request for an LCD in that it **is available only for final**

effective LCDs. The whole LCD or any provision of the LCD may be reconsidered. In addition, MACs have the discretion to revise or retire their LCDs at any time on their own initiative.

Web Site Requirements for the LCD Reconsideration Process 13.3.1 (New)

MACs shall add to their MAC Web sites information on the LCD Reconsideration Process. This information should be on the LCD home page of the MAC's Web site. It shall be labeled "LCD Reconsideration Process" and shall include:

- A description of the LCD Reconsideration Process; and
- Instructions for submitting LCD reconsideration requests, including postal, e-mail, and fax addresses where requests may be submitted.

Valid LCD Reconsideration Request Requirements 13.3.2 (New)

MACs shall consider all LCD reconsideration requests from:

- Beneficiaries residing or receiving care in a contractor's jurisdiction; and
- Providers doing business in a contractor's jurisdiction.
- Any interested party doing business in a contractor's jurisdiction.

MACs should only accept reconsideration requests for LCDs published as an effective final. Requests shall **not** be accepted for other documents.

If modification of the LCD would conflict with an NCD, the request would not be valid. The MAC should refer the requestor to the NCD reconsideration process. Requestors can be referred to http://www.cms.gov/DeterminationProcess/01_overview.asp#regs.

Requests shall be submitted in writing and shall identify the language that the requestor wants added to or deleted from an LCD. Requests shall include a justification supported by new evidence, which may materially affect the LCD's content or basis. Copies of published evidence shall be included. Any request for LCD reconsideration that, after MAC review, is determined to not meet these criteria is invalid. MACs have the discretion to consolidate valid requests if similar requests are received.

Process Requirements 13.3.3 (New)

The requestor shall submit a valid LCD reconsideration request to the appropriate MAC, following instructions on the MAC's Web site.

Within 60 calendar days of the day the request is received, the MAC shall determine whether the request is valid or invalid. If the request is invalid, the contractor shall respond, in writing, to the requestor explaining why the request was invalid. If the request is valid, the MAC shall open the LCD and follow the LCD process as outlined in section 13.2 of this manual or include the LCD on the MAC's waiting list. The MAC shall respond, in writing, to the requestor notifying the requestor of the acceptance, and if applicable, wait listing, of the reconsideration request.

Challenge of an LCD 13.4 (Revised)

In addition to creating the term "Local Coverage Determination" (LCD), section 1869(f) of the Social Security Act creates an appeals process for an "aggrieved party" to challenge LCDs/LCD provisions that

are in effect at the time of the challenge. “Aggrieved party” is defined in regulation as a Medicare beneficiary, or the estate of a Medicare beneficiary, who is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare Advantage plan (MA), or in another Medicare managed care plan), and is in need of coverage for an item or service that would be denied by an LCD, as documented by the beneficiary’s treating physician, regardless of whether the service has been received. An aggrieved party has obtained documentation of the need by the beneficiary’s treating physician.

LCD Content 13.5 (*Revised*)

General Requirements 13.5.1 (*Revised*)

The Medicare Coverage Database (MCD) is the central repository that houses proposed and final LCDs, and LCD related articles.

- The MACs shall publish all proposed and final LCDs and LCD related articles on the MCD. The public may access the MCD at <http://www.cms.gov/medicare-coverage-database>.
- MACs must ensure the accuracy of the information entered into the MCD.
- If a MAC decides to have LCDs and related articles on their MAC web sites, then the MAC must link from their MAC website to the MCD.

MACs shall **finalize or retire all proposed LCDs within a rolling year of publication date of the proposed LCD** on the MCD (365 days). If an unusual circumstance occurs and the MAC wishes to request an exception to this requirement, they shall notify their COR and LCD BFLs at least 21 business days before the one year expiration date.

The MAC shall ensure that all LCDs do not conflict with all statutes, rulings, regulations, and national coverage, payment, and coding policies.

For all new and revised LCDs MACs shall **no longer include national policy language** found in statute, regulations, rulings, interpretive manual instructions, etc. in the coverage and indications section of their LCDs. If contractors need to reference a national policy in the coverage and indications section of their LCD, they shall cite the reference (e.g. publication number, Medicare title of manual, section of manual) without reiterating the text from the policy.

It is no longer appropriate to include Current Procedure Terminology (CPT) codes or International Classification of Diseases-Tenth Revision-Clinical Modification (ICD-10-CM) codes in the LCDs. **All CPT and ICD-10-CM codes shall be removed from LCDs** and placed in billing & coding articles or Policy Articles that are to be published to the MCD and related to the LCD. CMS will provide additional instructions on the date upon which this change will be effective.

Consultation 13.5.2 (*Revised*)

The MAC shall summarize the opinions received as a result of consultation with healthcare professional expert(s), professional societies, etc. **prior to the drafting of a proposed LCD**, and include this information in the proposed LCD.

CAC Recommendations 13.5.2.2 (New)

When a MAC determines that a CAC consultation should be sought for a proposed LCD, the summary of recommendations from the CAC regarding the policy shall be included in the Final LCD.

Contractors shall clearly identify, attendance information consisting of location, time and, date for the CAC meeting(s) and ensure that these are clearly distinguished from the information for the Open meeting(s) even if they occur on the same day at the same location. The MAC shall also make available a means to accommodate reasonable requests for assistance from stakeholders who are hearing or visually impaired. The frequency of the CAC meetings are at the discretion of the MAC and will be based on the appropriateness and on the volume of LCDs that require CAC consultation as part of the LCD process.

Evidentiary Content 13.5.3 (Revised)

In every proposed and final LCD, the MAC must summarize the evidence that supports coverage, limited coverage, maintenance of existing coverage in cases of LCD reconsideration or non-coverage. At a minimum, the summary should include the following:

- a complete description of the item or service under review;
- a narrative that describes the scientific evidence supporting the clinical indications for the item or service;
- the target Medicare population; and
- whether the item or service is intended for use by health care providers or beneficiaries.

If the item or service is regulated by the FDA, and determined by the MAC to be reasonable and necessary, information regarding the use of the item or service subject to the FDA indication, as applicable, shall be included. MACs have the option of providing a hyperlink to the FDA clearance to market to meet this requirement.

In conducting a review, MACs shall use the available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines. Proprietary information, submitted by a requestor, not available to the public shall not be considered. Medicare data considered as part of the evidence review for an LCD shall be reported in the evidence summary. The reported data shall comply with Medicare Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule data disclosure requirements.

MACs shall list all articles and sources that led to the LCD in the Bibliography. The citations shall be consistent with the American Medical Association (AMA) Manual of Style.

MACs shall explain the rationale that supports their coverage determination of covered, non-covered, or limited coverage. The rationale is the reasoning leading to the coverage determination.

If it is appropriate for a MAC to provide coding/billing information to help implement the coverage policy, MAC shall publish the coding/billing article at the same time they publish the proposed LCD.

Reasonable and Necessary Provisions in LCDs 13.5.4 (*Revised*)

Contractors shall determine and describe in the LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall determine if evidence exist to consider an item or service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

Public Comment 13.5.5 (*New*)

MACs are required to provide a minimum of 45 calendar days for public comment on all proposed LCDs. MACs shall respond to all timely received public comments, and may group similar comments and responses in logical categories in the RTC article.

Final Decision 13.5.6 (*New*)

MACs shall finalize or retire all proposed LCDs within a rolling year of publication date of the proposed LCD on the MCD (365 days). After the close of the comment period and the required meetings, the MACs shall publish a final LCD to the MCD. MACs shall link from their contractor website to the final LCD on the MCD.

As stated earlier, the MAC shall also respond to all comments received, via the RTC article which shall be published on the MCD and be related to the LCD. The RTC article shall be displayed at the same time as the final LCD.

MACs shall notify the public that a final decision has been published and provide the Web link to the final decision.

LCD Record 13.6 (*Revised*)

The LCD record shall be maintained by contractors for **a minimum of 6 years and 3 months from the date the LCD is retired**. Contractors shall have a mechanism for archiving retired LCDs. This mechanism shall also allow the contractor to respond to requests and retrieve the LCD record. After 6 years and 3 months from the date the LCD is retired, the LCD record shall be destroyed. However, contractors shall not destroy the LCD record if it relates to a current investigation of litigation/negotiation; ongoing Workers' Compensation set aside arrangements; or documents which prompt suspicions of fraud and abuse of items or services. This will satisfy evidentiary needs and discovery obligations critical to the agency's litigation interests.