Local Coverage Determination (LCD) Process Modernization
Qs & As

Q1: What is a Local Coverage Determination (LCD)?

A1: An LCD, as defined in §1869(f)(2)(B) of the Social Security Act (SSA), is a determination by a Medicare Administrative Contractor (MAC) regarding 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.

Q2: **What local coverage determination (LCD) process modernization changes has the Centers for Medicare & Medicaid Services (CMS) made?**

A2: CMS has revised the Medicare Program Integrity Manual (PIM), Chapter 13 – Local Coverage Determinations (Pub 100-08). The link to this section of the manual can be found at: https://www.cms.gov/Regulations-and- Guidance/Guidance/Manuals/Downloads/pim83c13.pdf. MACs are organizations that have statutory authority to develop LCDs for their individual jurisdictions. Chapter 13 of the PIM outlines the LCD process, which has now been updated to serve as a roadmap for MACs. The new process provides greater transparency, consistency and patient engagement, as well as supports larger CMS innovation initiatives. The revised PIM guides stakeholders by describing the process, what to expect, and how to provide feedback to MACs. It also clarifies CMS's expectations for MACs.

Q3: Why was Chapter 13 of the PIM updated?

A3: Last year, CMS engaged directly with stakeholders to solicit ideas that could reduce administrative burden and improve the Medicare program. Improvements to the LCD process were suggested in response to the **CMS–1676–P -** CY 2018 Physician Fee Schedule Request For Information (RFI) found at: https://www.govinfo.gov/content/pkg/FR-2017-07-21/pdf/2017-14639.pdf). Many of the LCD process changes recommended by the public could be aligned with process changes already underway as a result of the statutory mandates of the 21st Century Cures Act of 2016 (Public Law 114-255).

Q4: What are specific statutory mandates of the 21st Century Cures Act of 2016 (Public Law 114-255)?

A4**:** The 21st Century Cures Act of 2016 added language to section 1862(l)(5)(D) of the Social Security Act (the Act) directing the Secretary of the Department of Health and Human Services (DHHS) to improve the transparency of the LCD process. Specifically, at least 45 days before the effective date of a new LCD determination, MACs must post the following information on their websites and in the Medicare Coverage Database (MCD):

- The entire determination.
- Where and when the proposed determination was first made public.
- Web links to the proposed determination and a response to comments submitted to the MAC about the proposed determination.
- A summary of evidence considered by the MAC during the development of the determination, and a list of the sources of such evidence.

- An explanation of the rationale that supports the determination.

Q5: In addition to the changes made to comply with 21st Century Cures Act, what are the other major changes that were made to the PIM chapter 13?

A5: The following are some of the LCD process changes found in the manual:

- **Clear process "roadmap."** A step-by-step description of the LCD process in language that is accessible to all stakeholders. 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 (CAC), final determination, and the notice period.

- **Requirement for consistent presentation of evidence.** Standardized summary of clinical evidence supporting LCD decisions and a MAC coverage determination rationale.

- **Guidance for informal meetings with MACs.** Option to request an *informal meeting* with the MAC to discuss potential LCD requests.

- **New LCD request process.** An explanation of the process and requirements by which interested parties in a MAC jurisdiction can request a *new* LCD.

- **Explanation of the purpose and new requirements for the restructured CAC meetings.** Meetings are now open to the public. CAC members serve in an advisory capacity as representatives of their constituency to review the quality of the evidence used in the development of an LCD. MACs can host CAC meetings in various ways (in-person, telephone, video, webinar). MACs determine how frequently these meetings occur based on the appropriateness and volume of LCDs requiring CAC input. MACs have the option of hosting CAC meetings prior to the posting of a proposed LCD to assist in the upfront analysis of the evidence or hosting the CAC after the publication of the proposed LCD. MACs also now have the option of convening multi-jurisdictional (one MAC with oversight of multiple jurisdictions) CACs or multi MAC (several different MACs) CACs.

  - **More voices on CAC.** In addition to physicians, other healthcare professionals (e.g., nurses, social workers, epidemiologists) can participate in the CAC. The CAC also must include beneficiary representation.

- **Requirements for repurposed public meetings.** Open meetings in the MAC jurisdiction to present proposed LCDs, including evidence and rationale of decisions. MACs clearly identify the location, dates and conference information (such as, telephone, webinar) and distinguish these open public meetings from CAC meetings.

- **Guidance around "old" proposed policies.** Proposed policies are retired if not finalized within 1 year of the original posting date.

- **Relocation of codes.** Healthcare Common Procedure Coding System (HCPCS), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) and Current

Procedure Terminology (CPT) codes will be removed from LCDs in the future. (Also see Q13-Q18)

- **Requirements for better communication.** MAC responses to public comments are linked to the final LCD and remain in the MCD (archives) indefinitely. MACs notify the public when they publish a final decision and provide a web link to it.

- **Consistent reconsideration process.** 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 is consistent with the National Coverage Determination reconsideration process. MACs must follow the full LCD process for valid reconsideration requests.

Q6: Is a CAC required for every LCD reconsideration or new LCD?

A6: No, a CAC is not required for every LCD reconsideration or new LCD. PIM Chapter 13 Section 13.5.2.2 states "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."

Q7: Do CAC meetings have to be held during the comment period?

A7: No, there are no contractor requirements that state that a CAC has to be held during the comment period. MACs have the option of holding their CAC meetings before or after the publication of the proposed LCD. The purpose of holding a CAC prior to the issuance of a proposed LCD and comment period is to evaluate the body of evidence and address specific evidentiary questions, which will serve as the basis for the formulation of the determination identified in the proposed LCD. 21st Century Cures Act requires that the LCDs include a summary of the evidence the MAC considered to make their determination along with an explanation of the rationale that supports their determination. Therefore, we believe the role of CAC members should evolve to include reviewing the quality of the evidence used to develop LCDs instead of only representing their constituency as an advisor. We believe that CAC advice is most useful when it comes from a process of full scientific inquiry and thoughtful discussion.

Q8: Regarding the new requirement to record and transcribe CAC meetings, and post them online, what were the reasons for that change? What stakeholders from outside CMS asked for this change?

A8: It is common practice for public meetings to be captured for the record. Having a record of a meeting affords those who were unable to attend to still be informed and therefore allows for greater engagement during public comment. This is in alignment with overall CMS priorities to increase transparency and stakeholder engagement. Multiple stakeholders have requested greater transparency for the local coverage process. Last year, CMS engaged directly with stakeholders to solicit ideas that could reduce administrative burden and improve the Medicare program. Improvements to the LCD process were suggested in response to the CMS–1676–P - CY 2018 Physician Fee Schedule Request For Information (RFI) found at: https://www.govinfo.gov/content/pkg/FR-2017-07-21/pdf/2017-14639.pdf). Additionally we met with and received feedback from the American Medical Association, AdvaMed, the American Clinical Laboratory Association, and the College of American Pathologists and stakeholders via an email address specifically set up to receive stakeholder feedback.

Q9: Can MACs have multi-jurisdictional Open Meetings?

A9: Yes, nothing in PIM, Chapter 13 precludes MACs from developing efficient processes to maximize stakeholder participation in an Open Meeting, which may include hosting multi-jurisdictional (one MAC with oversight of multiple jurisdictions) Open Meetings. The intent of the Open Meeting is to ensure MACs discuss the review of the evidence and the rationale for the proposed LCD(s) with stakeholders in those jurisdictions that may be impacted by a policy change.

Q10: How did stakeholder input factor into the updated PIM, chapter 13?

A10: Many of the changes are statutory mandates; other changes were suggested in response to the RFI or in correspondence with CMS.

Q11: Will providers feel comfortable providing honest recommendations to MACs when their opinions are open to the public, pharmaceutical companies and other health service and supply vendors?

A11: Through the RFI process and other correspondence, CMS heard loud and clear that many stakeholders want more transparency in the LCD process. We hope that providers will be comfortable stating their professional opinions about which services should and should not be covered and expect that they use clinical evidence to support their opinions. CMS is open to refining the process further as needed.

Q12: Will the more extensive comment process outlined in the revised PIM, Chapter 13 delay approvals for new technologies?

A12: We expect the more extensive comment process to pave the way for better and more equitable patient care, including more beneficiaries having access to new technologies. We believe balancing transparency and stakeholder feedback with the overall LCD process timeline is important. Therefore, we now require that MACs typically finalize or retire all proposed LCDs within a rolling year of publication date of the proposed LCD (365 days). CMS is open to refining the process further as needed. If a stakeholder wishes to submit comments on the LCD Modernization changes, please submit your email to: LCDManual@cms.hhs.gov.

Q13: Under the revised PIM, Chapter 13, would MACs be able to issue a new LCD/related policy article to non-cover particular items and services or a category or class of technologies (for example, technologies with Category III, PLA or MAAA codes) without conducting an analysis of the evidence and providing a rationale for the determination?

A13: MACs must follow the revised LCD process to make any changes in coverage, which includes analyzing the evidence and providing a rationale for the determination with respect to the item/service/technology. In March 2020, MACs were given direction to retire all Non-Covered Services/Category III CPT® code LCDs, related articles, and applicable auto-deny edits by July 1, 2020. This direction also reiterates that the MACs must follow the established LCD process found in PIM, Chapter 13 when developing LCDs that articulate when an item/service/technology is considered reasonable and necessary (R & N) or use claim by claim medical record review to determine R & N coverage. This action is an extension of the direction we gave the MACs and shared with the public in April 2019.

Q14: When can the public expect to see the LCD content changes outlined in the new PIM?

A14: The majority of content changes have now been implemented for all new proposed or revised policies. **Please note:** CMS's new policy approach is that LCDs will no longer include diagnosis and procedure codes, HCPCS codes, CPT codes or ICD-10-CM codes within the coverage determination statement. All HCPCS, CPT and ICD-10-CM codes will 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 is actively working on the plan to accomplish this transition. We expect these content changes to be made on a flow basis and MACs are now preparing the code transitions.

Q15: Are there anticipated differences in the LCD content between A/B MAC LCDs and Durable Medical Equipment MAC (DMEMAC) LCDs?

A15: DMEMAC LCDs will continue to contain procedure codes. Procedure codes in A/B MAC policies will be moved to articles as indicated in Q14.

Q16: Will the relocation of codes from LCDs to articles impact the availability of downloadable LCD Data that is available in the Medicare Coverage Database: https://www.cms.gov/medicare-coverage-database/downloads/downloadable-databases.aspx Or, will the downloadable data still remain as is?

A16: No, the relocation of codes will not impact the availability of downloadable LCD data. Codes that are removed from the LCDs and subsequently moved to the Articles will be downloadable from the Articles.

Q17: **The decision to no longer include CPT/ICD-10 codes in the LCDs in the future was made to "promote harmonization between local and National coverage processes." Can you expand on this reasoning? Is there any concern that removing the codes from the LCD, and not placing them on the website, will make the codes less easily accessible? Will the status of what codes are covered and which aren't have the same accessibility and clarity with the codes placed in the billing and coding articles?**

A17: National coverage determinations have not contained codes since 2006. Generally speaking, codes are a reflection of the operationalization of a policy. The policy is the NCD or LCD itself. By relocating codes to billing and coding articles on the Medicare Coverage Database, the codes can be efficiently and promptly maintained when coding changes (revisions, retirement, additions) occur (annually or quarterly for some code sets) without requiring a reconsideration of the LCD. To make the relocation seamless for the public, these articles will be directly linked to the LCD policy. This also allows coders and others to easily filter the database to find just the information they need. The one exception to code relocation is DME LCDs. Due to the nature and scope of DME LCDs, these policies do retain some coding within the policy itself.

Q18: **Did all PIM, Chapter 13 changes take effect on Jan. 8, 2019 or are they still being phased in?**

A 18: All MACs are in action operationalizing the changes resulted from the new PIM, Chapter 13. Some changes, like code relocation, are taking place on a flow basis. Changes for existing policies are contingent upon database upgrades which are in development now. The expectation is that every current LCD will have codes relocated to coding and billing articles or the equivalent by the beginning of 2020.