



COLLEGE of AMERICAN PATHOLOGISTS

February 23, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
The Honorable Jon Blum
Principal Deputy Administrator & Chief Operating Officer
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure and Principal Deputy Administrator Blum:

The CAP and its network of Contractor Advisory Committee (CAC) representatives have monitored the Local Coverage Determination process since CMS made its revisions to the LCD guidelines in 2019.¹ During that time we have observed several issues of concern regarding development and delivery of sound and timely Medicare local coverage policy. The CAP, at times in concert with other organizations, has respectfully and repeatedly appealed for redress of the issues we identified, which are outlined in this letter and in previous letters and meetings with CMS since 2020. Specifically, our issues include insufficient opportunity for CAC engagement in the LCD development process, narrow focus of Medicare contractor open public meetings, protracted timeframe for competing reconsideration requests of LCDs, no comment period or opportunity for public decision-making for changes to Local Coverage Articles (LCAs) that impact coverage, and lack of MAC metrics for adhering to the LCD process.

We appreciate CMS's flexibility and interest in guiding the local coverage process. However, as a result of CMS' 2019 revisions to the LCD guidelines, we believe that the elements critical to ensuring sound local coverage policy have been compromised. As such, we respectfully urge CMS to consider the following concerns and recommendations that we believe, through our observations and participation in the LCD process, have contributed to the decline in local coverage decision-making.

1. Insufficient Opportunity for CAC Engagement in the LCD Development Process

The CAC is a long-standing CMS mechanism for physicians in each state to serve in an advisory capacity as representatives of their constituency in local coverage decision making. CMS deems physician participation an important supplement to a MAC's internal expertise when developing LCDs. CMS acknowledges that CAC members are valued for their background, education, experience and expertise in a wide variety of scientific, clinical and other related fields. (PIM, Chap. 13, §13.2.4.3). Nonetheless, Medicare Administrative Contractors (MACs) have systematically omitted CAC representatives from the LCD development process. Following CMS' 2019 revisions to

¹ Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.8.1.1, ((Rev. 863, 02-12-19).



the LCD guidelines, the role of the CAC has diminished to where its members no longer have an opportunity to engage in interactive discussions with contractor medical directors of new and revised LCDs, nor is their expertise sought by the MACs. As such, local coverage decisions fall short of their potential by excluding the clinical knowledge of practicing physicians and the needs of patients within specific jurisdictions which are critical for shaping local coverage determinations. Through experience participating in the LCD process, the CAP and its CAC members have observed several factors that have contributed to the decline in CAC engagement.

Redefinition of the role of CAC representative: Prior to the 2019 revisions to the LCD guidelines, CMS defined the purpose of the CAC meeting as a formal mechanism for physicians to “*be informed of and participate in the development of an LCD in an advisory capacity.*” MACs were required to communicate to CAC members that *the focus of the CAC was LCDs and Medicare administrative policies.*² However, the 2019 revised LCD guidelines describes the role of the CAC as a formal mechanism for healthcare professionals “*to be informed of the evidence used in developing the LCD*” and that CAC members now serve in an advisory capacity as representatives of their constituency “*to review the quality of the evidence used in the development of an LCD.*”

Some MACs have literally interpreted this to mean that the sole role of a CAC representative is to judge the strength of the evidence used to develop an LCD. The implicit redefinition of CAC representatives represents both a mischaracterization of their role and a loss of what they uniquely and necessarily bring to the local coverage process as physician experts who daily engage in patient care with various patient populations. Our CAC representatives have observed that even when their expertise is offered it does not appear to be meaningfully considered by the MACs. This failure by CMS and MACs to recognize the nexus between a coverage topic and the expertise that practicing physicians bring to coverage policy development can result in less than optimal coverage policies and reduced access to care for patients.

Optional CAC meetings: CAC meetings are now at the discretion of the MAC whereas prior to the 2019 revised LCD guidelines MACs were required to hold a minimum number of CAC meetings per year to discuss draft LCDs and other Medicare-related issues. As a result, meetings now occur less frequently, randomly, or not at all, which further illustrates how contractors have deprioritized CAC engagement and devalued their advisory responsibilities. Additionally, these meetings which were once held at the end of the workday now usually take place on weekday afternoons, posing a further challenge for CAC members to participate.

We recommend that MACs take a more aggregate view of LCD development including published evidence as well as clinical expertise that physician CAC representatives have to offer.

² Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.8.1.1, ((Rev. 608, 08-14-15)



2. Open Public Meetings

As stated in the LCD guidelines, the intent of open public meetings is to discuss the review of evidence and rationale for proposed LCDs with stakeholders in the MAC jurisdiction, and to allow stakeholders to make presentations of information related to the proposed LCDs. MAC open meetings have attempted to follow the MEDCAC NCD model but in seeking to parallel the very differently resourced NCD process, MAC open meetings fall short of that model. Unlike MEDCAC, MAC open meetings are narrowly focused on subject expert testimony of published evidence and do not always provide an opportunity for stakeholder discussion about the needs of patient populations and the kinds of value judgements by physicians that are necessary to treat patients. Published studies do not always comprehensively address the needs of patients, particularly with multiple diseases. While MACs rely on scientific data to drive coverage policy, practicing physicians are well positioned to convey both the application of evidence within the context of clinical practice as well as their independent medical judgment needed to determine a patient's care or treatment. Open public meetings should be an opportunity for all stakeholders to identify and address issues related to the scientific evidence, clinical practice, and the needs of patients within the context of a coverage policy. These important discussions can yield information and recommendations that are essential for more sound coverage policies.

We therefore recommend CMS require MAC open meetings to provide a more open forum for information exchange between MACs and stakeholders on new or revised LCDs. Stakeholders are generally those that would be affected by the LCD, including providers, physicians, vendors, manufacturers, beneficiaries, and caregivers.

Additionally, our physicians have observed that notice periods for open meetings can vary by MAC and that shorter-range calendar dates do not always allow sufficient time for stakeholders to prepare their presentation materials.

We recommend CMS establish a minimum period of three weeks between posting an open meeting notice and the date of the meeting.

3. Reconsideration Request Timelines

Current LCD guidelines do not provide a timeframe for MACs to complete a reconsideration request for a revision to a local coverage determination. For valid reconsider requests, MACs re required to reopen the LCD and follow the LCD process as outlined in the LCD guidelines or add the LCD to the MAC's waiting list. (PIM, Chap. 13, §13.3.3). Some MACs have a large backlog of new policies thus, reconsiderations can take months or even longer, as illustrated by the following.



COLLEGE of AMERICAN PATHOLOGISTS

On December 31, 2021, the CAP filed a formal reconsideration request for revisions to the Special Histochemical Stains and Immunohistochemical Stains LCD. The request was sent independently to four MACs with the identical special stains LCD. In 2023, three MACs issued their proposed changes to the LCD at different times, followed by the mandatory open meetings and public comment periods. However, no final LCD has yet been published by those MACs. Further, there has been no communication from the fourth MAC subsequent to its confirmation on January 7, 2022, that our request was valid. Our request includes the removal of the outdated age-based and clinical criterion-based selection for testing colorectal cancer patients which is supported by updated NCCN clinical practice guidelines. Meanwhile, the outdated coverage policies that are currently in effect are denying critical cancer tests to Medicare patients.

While MACs generally apply the reconsideration process in a manner that conforms with existing LCD guidelines, the LCD guidelines no longer provide sufficient guidance and oversight to ensure requests are finalized in a timely manner. Reconsideration requests typically apply to only a single, outdated coverage provision within an LCD and therefore should be given priority over future LCDs that are in development or are waitlisted. Additionally, the process lacks transparency regarding the status of reconsideration requests.

We recommend that MACs be required to issue a final LCD on valid reconsideration requests within 180 days from the date the public comment period ends. We further recommend that MACs post a tracking sheet to their website with timely disclosure of information appropriate to reconsideration requests.

4. Opportunity for Public Comment of Local Coverage Articles that Impact Coverage

The CAP continues to hear from its members about other LCD process concerns, including the lack of a public comment period or opportunity for public decision-making of changes to Local Coverage Articles (LCAs). As part of CMS's 2019 process changes, LCDs no longer include diagnosis and procedure codes, HCPCS codes, CPT codes or ICD-10-CM codes within local coverage determinations. In many cases, coverage for an item or service depends on whether a specific code is specified in a Local Coverage Article (LCA). While MACs may seek public comments on an LCA that accompanies a draft LCD, many LCAs do not have an accompanying LCD and are not subject to public review and comment prior to publication.

Currently, there is no requirement that MACs implement a notice period for coding updates to LCAs when the updates impact coverage. As such, providers may be subject to essentially new coverage requirements and restrictions. Furthermore, the lack of a notice period prior to implementation of changes to LCAs does not allow time for providers and billing staff to familiarize themselves with the new coding requirements, update their IT systems to accommodate the changes, and/or raise concerns about coverage with contractors. This places significant burden on providers and increases the



risk of improper billing and potential harm to patients if LCAs inappropriately restrict coverage of medically necessary services.

We recommend that CMS require new LCAs or coding updates to existing LCAs that reflect non-routine changes in coding and that impact coverage, are subject to public notice and comment before new or revised LCAs take effect.

5. MAC Metrics for Adhering to the LCD Process

The Medicare Access and CHIP Reauthorization Act of 2015 set forth a provision in Section 509 that requires contractor performance transparency to the extent possible without compromising the process for entering into and renewing contracts with Medicare Administrative Contractors (MAC).³ Under this section, the Secretary shall make available to the public the performance of each MAC with respect to such performance requirements and measurement standards.

The LCD process is a large component of each Part A/B MAC contract with CMS, and as such, the CAP believes that CMS should implement and publicly report performance metrics that hold MACs accountable for adhering to applicable LCD guidelines outlined in Chapter 13 of the Medicare Program Integrity Manual. Current performance metrics for MACs do not include measures to assess if a MAC is fulfilling these requirements in substance or in form only.

Therefore, we recommend that CMS add key LCD process measures to the current MAC performance metrics to assess performance effectiveness and adherence to specific LCD guidelines and as outlined in MAC contracts.

Thank you for your consideration of our comments. We will be reaching out to formally request a meeting, but if you have any questions or would like additional details on the information in this letter, please do not hesitate to contact Nonda Wilson, MS, Manager for Economic and Regulatory Affairs at the College of American Pathologists, at nwilson@cap.org. or 202-354-7116.

³ Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. 114-10, 129 Stat. 87, 2015. Available at: <https://www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf>