COLLEGE of AMERICAN PATHOLOGISTS

September 20, 2024

Dora L. Hughes, M.D., M.P.H.
Acting Director,
Center for Clinical Standards and Quality
Chief Medical Officer
Centers for Medicare & Medicaid Services

Dear Dr. Hughes,

Thank you for your response to our letter of March 2024, for ways to improve the LCD process.

We appreciate the information you provided about the different types of Articles in the Medicare Coverage Database (MCD) and the recent changes to the MCD that make it easier to distinguish between Billing and Coding Articles that support LCDs from other types of Articles. We also appreciate that CMS strongly encourages MACs to issue Billing and Coding Articles at the same time a proposed LCD is issued, despite this not being a requirement. This provides the public an opportunity to summit comments on the guidelines and billing codes during the LCD public comment period and helps to avoid the additional process of requesting a reconsideration of the LCD.

We understand that CMS has redefined the role of CAC representative and the CAP is committed to working with CMS to fashion a role for CAC members and physicians that provides meaningful opportunities for engagement in the LCD process. As such, we are pleased to learn that you agree that MAC open public meetings should be an opportunity for all physicians and other stakeholders to identify and address issues related to the scientific evidence, clinical practice, and the needs of patients within the context of a local coverage policy. It is especially important that open meetings allow an opportunity for practicing physicians attending the meetings to also ask questions of speakers and offer commentary on the clinical implications of a coverage policy. This process parallels the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meetings that advise CMS on national coverage policy which, in addition to evaluating evidence, permits statements from clinical practitioners, test and device manufacturers, and patient advocates.

In response to your request for examples of MAC open public meetings that are not conducted in a manner consistent with this intent, I refer you to the following descriptions of open meetings that are on MAC websites (bold text added for emphasis). Additionally, CAP staff and its CAC members have attended dozens of open meetings and can attest to their restriction to 'evidence only' discussions and the lack of opportunity for physicians and other stakeholders attending to ask questions of the speakers or offer comments.

> *Palmetto GBA: Palmetto will periodically host open meetings to discuss the **scientific evidence** underlying proposed LCDs. Interested parties from within the jurisdiction may attend and orally present information related to the proposed LCDs*

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*CGS: Open Meetings are for the **evidentiary review of literature** for draft LCDs.*

*Noridian: To ensure the development of LCDs occurs through a public and open process, we are soliciting **scientific evidence** and other **scientific-based information** related to the proposed LCDs, from the general public and members of the Contractor Advisory Committees.*

*NGS: To ensure the development of LCDs occurs through a public and open process, we are soliciting **scientific evidence** and other **scientific-based information** related to the proposed LCDs, from the general public and members of the Contractor Advisory Committees.*

In addition to open meetings, MACs hold multijurisdictional CAC meetings that are not defined in the LCD guidelines but are used to help inform local coverage policy. These multijurisdictional CAC meetings are for the purpose of obtaining advice from a panel of experts that include CAC members and subject matter experts about the quality of published evidence for a specific topic. In your letter you state that following enactment of the 21st Century Cures Act, CMS decided to align the CAC process with the MEDCAC, in which experts review evidence that informs policy development. Accordingly, MAC multi-jurisdictional CAC meetings should require the same level of transparency as MEDCAC meetings. However, unlike the MEDCAC process the MAC evidentiary meetings lack transparency. In addition to announcing the topic for discussion, MACs should define and employ criteria for vetting and selecting panel members, including qualifications for panel participation. MACs should also describe the specifics of what they are looking for from panel members, similar to the information CMS provides in the Federal Register for MEDCAC meetings. For example, CMS' Federal Register meeting announcement for Chimeric Antigen Receptor (CAR) T-cell therapies clearly stated that CMS was seeking the MEDCAC's recommendations regarding collection of patient reported outcomes in cancer clinical studies and that MEDCAC would specifically focus on appraisal of evidence-based PRO assessments.[1] This type of information provides important guidance to the CAC and other stakeholders when considering participating or recommending someone for participation in a MAC evidentiary panel.

The CAP appreciates that MACs need the flexibility to ensure an evidentiarily sound LCD is developed that meets the needs of Medicare beneficiaries. However, a reasonable timeframe for completing LCD reconsideration requests is necessary to keep pace with advances in science and to provide Medicare beneficiaries with the tests and services they need. As we described in our March letter, the CAP requested reconsideration of Noridian's Special Histochemical Stains and Immunohistochemical Stains LCD in December 2021, and received confirmation in January 2022, that the request was valid. However, since that time Noridian has not proposed any updates to its policy, which other MACs have since acknowledged and implemented. Despite ample new evidence to support coverage updates to several areas of the LCD, Noridian's policy remains outdated and denies necessary tests and services to Medicare beneficiaries. In consideration of this example we recommend that MACs finalize all reconsideration requests within one rolling year from the date a MAC

deems a reconsideration request valid. This timeframe is in keeping with the LCD guidelines that require MACs to finalize or retire all proposed LCDs within a rolling year (365 days) of publication date of the proposed LCD. (PIM, Chap. 13, §13.5.1). Additionally, greater transparency of the reconsideration process is needed so that the public can monitor the status of a request. We recommend that for valid reconsideration requests, MACs make available on their websites or on the Medicare Coverage Database the subject of the request, any extension that may be granted to the timeframe for completing a request, and the length of the extension.

Lastly, the CAP appreciates that CMS is willing to consider adding some key LCD process measures to the current MAC performance metrics to assess performance effectiveness and adherence to specific LCD guidelines. As such, we provide the following for your consideration:

- Consistency among MAC open public meetings that allows stakeholder discussion of the scientific evidence, clinical practice, and the needs of patients as it relates to an LCD.
- MAC transparency and use of objective criteria for vetting and selecting subject matter experts for participation on select evidentiary panels.
- Adherence to the requirement that MACs establish a CAC (either one per jurisdiction or multi-jurisdiction) and that MACs maintain a current list of its CAC members.
- Adherence to the established one-year timeframe for completing LCDs and LCD reconsideration requests, unless an extension is granted by CMS.

Thank you again for considering our comments. The CAP remains committed to working with CMS to improve the LCD process and we look forward to hearing from you. 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.

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[1] Federal Register 27993, Vol. 83, No. 116, Friday, June 15, 2018