July 23, 2024

The Honorable Chiquita Brooks-LaSure Administrator

Centers for Medicare and Medicaid Services 7500 Security Boulevard

Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

Thank you for your letter and investigation in response to our concerns about the Palmetto GBA MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma Local Coverage Determination ([L39345](https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39345&ver=3&lcdStatus=A&sortBy=title&bc=6)). We appreciate your commitment to an open LCD process that ensures Medicare beneficiaries have appropriate access to innovative molecular diagnostic testing. However, your consideration of adherence to the appropriate LCD development process misses the specific issue we have with this LCD – that it improperly limits the scope and defines the practice of medicine by board-certified pathologists, licensed physicians and surgeons, who are eligible to order laboratory tests. As we outlined in our March 1, 2024 letter, imposing restrictions, as a condition of coverage, as to the subspecialty qualifications of those who can order certain tests presumes to characterize the training and determine the competencies of board-certified physicians and sets a dangerous precedent with the potential to limit access to necessary care for Medicare patients.

At your urging and Palmetto’s invitation, the CAP met with Palmetto in good faith believing we would have the opportunity to discuss these concerns with the MAC. We were disappointed when Dr. Gabriel Bien-Willner, Molecular Diagnostic Services (MolDX) Program Medical Director, stated at the start of the meeting that we were “wasting our breath” talking about “legal arguments” and that he would only discuss practical issues related to the LCD such as real-life examples of access to care or harm to patients. We understand that a MAC’s responsibility is to write policies for reasonable and necessary services, and that the purpose of the MolDX LCD was specifically to assist with the accurate diagnosis of challenging lesions using dermatopathology expertise. We further understand that Palmetto wants to ensure that the molecular tests are appropriately used in the correct context and that expensive tests should not be ordered on a “whim” or in lieu of a consultation with a dermatopathologist. **However, scope of practice restrictions in LCDs are not an appropriate – nor are a permitted – approach to addressing utilization issues**.

It is incumbent upon pathologists to make sure the right tests are available to provide quality diagnostic services to patients and to practice responsible utilization management. Unfounded concerns of rampant overutilization must not be a basis for a blanket coverage policy that improperly imposes limits on physician decision-making and infringes on the practice of medicine through scope of practice restrictions. Furthermore, there is no evidence supporting the supposition that there is more inappropriate utilization of ancillary testing by general as opposed to subspecialty pathologists. As we explained to Dr. Bien-Willner, in addition to being inappropriate, these restrictions may result in scenarios whereby access to testing could be delayed when complying with the language of the LCD. For example, we asked Palmetto to clarify whether a pathologist is allowed to order a molecular test following a consultation with a dermatopathologist who agrees with the pathologist that further testing is needed. Dr. Bien-Willner confirmed that the policy is written such that a dermatopathologist must order the test and he acknowledged that Palmetto had not considered all scenarios that might cause delays in testing. Moreover, MACs should not wait until there is actual patient harm before addressing those concerns. This kind of rationale can negatively impact the future care of Medicare beneficiaries.

Further, as we stated in our comment letter to you in March, our primary concern is about federal regulations governing MAC scope of authority. **The practice of medicine is regulated by individual states and it is not the purview of a MAC to countermand state statutes governing physician scope of practice. This concept is preserved in the Medicare Act, 42 U.S.C. §1395, which prohibits any federal interference with the “supervision or control over the practice of medicine or the manner in which medical services are provided.”** As Dr. Bien-Willner aptly pointed out, Medicare coverage is limited to items and services that are reasonable and necessary as outlined in section 1862(a)(1)(A) of the Social Security Act. States have specific authority to supervise and decide the scope of practice of each medical profession within their state. In every state, physicians can broadly practice medicine under the law. The CAP is not aware of any licensing authority that would constitute a basis for Palmetto’s subspecialty requirement that attempts to supersede statutes in over 23 states. Additionally, the Medicare Benefit Policy Manual Chapter 15, section 80.6.5, notes that there are additional tests that a pathologist may need to perform after an initial examination or interpretation, “even though they have not been specifically requested by the treating physician/practitioner,” so that a complete and accurate diagnosis can be reported to the treating physician/practitioner.

Pathologists who are board-certified in anatomic pathology routinely diagnose skin nevi and melanomas and are fully qualified to determine when molecular testing is necessary to help arrive at a correct diagnosis. Both the American Board of Pathology and state medical boards recognize that board-certified pathologists, without subspecialty certification, are qualified to perform and interpret a wide range of diagnostic tests and specimens, including molecular and dermatopathology.

Again, for the reasons outlined above, we request that the subspecialty requirement in LCD #L39345 – that any molecular test approved for coverage under the LCD be ordered by a board-certified or board-eligible dermatopathologist – be removed from the coverage policy and CMS work with its MACs to ensure local coverage policies do not violate federal regulations by limiting the scope of practice of board-certified pathologists or any other licensed physicians and surgeons who are eligible under state licensure laws to order laboratory and molecular tests required for the care and treatment of their patients.

We would appreciate the opportunity to engage with you further regarding MAC scope of authority. If you have any questions or would like additional information that would be helpful please contact Nonda Wilson, Manager, Economic and Regulatory Affairs, [nwilson@cap.org](mailto:nwilson@cap.org) at 202-354-7116.

Sincerely,

College of American Pathologists

Attachments

CMS letter to AMP/CAP, April 15 ,2024

AMP-CAP letter to CMS, March 1, 2024