March 1, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

The Association for Molecular Pathology (AMP) and the College of American Pathologists (CAP) are writing to express great concern about Palmetto GBA's Local Coverage Determination (LCD) "MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma (L39345)."[1]

The AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics.

The CAP is the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs. The CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

Our organizations understand the importance of patient safety and access to care. However, we believe this LCD improperly attempts to limit the scope and define the practice of medicine by board-certified pathologists, by imposing restrictions, as a condition of coverage, as to the subspecialty qualifications of those who can order certain tests. Specifically, this LCD imposes the requirement that any molecular test approved for coverage under the LCD be ordered by a board-certified or board-eligible dermatopathologist. Therefore, the AMP and the CAP request that the subspecialty requirement in LCD #L39345 be removed immediately from the coverage policy and that CMS ensure Medicare contractors do not exceed their scope of authority when developing future coverage policies.

We understand that some developers of proprietary tests promote their tests as a way to "assist dermatopathologists" in diagnosing melanocytic lesions and certainly, laboratories may develop their own quality assurance plan, protocols, and policies around this kind of detail. However, by taking this language and applying it as a requirement in an LCD, Palmetto is ignoring the extensive training and competencies of board-certified pathologists and misusing the subspecialty certification program. As we stated in our comment letter on the draft LCD, pathologists who are board-certified in anatomic pathology routinely diagnose skin nevi and melanomas and are fully qualified to determine when this test is necessary to help arrive at a correct diagnosis. Further, the American Board of Pathology (ABP) has previously emphasized that: "The achievement of subspecialty certification does not reflect on the ability of other pathologists to practice in that area." Both the ABP 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 malignant dermatology.

Additionally, the practice of medicine is regulated by individual states, and it is not within the Medicare Administrative Contractor (MAC) purview to interfere with 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."[2] Further, 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.[3] States supervise and license physicians and other health care providers and clinicians, and decide the scope of practice of each medical profession within the state. In every state, physicians can broadly practice medicine under the law. The AMP and the CAP are not aware of any licensing authority that would constitute a basis for Palmetto's subspecialty requirement.

Finally, we would also emphasize that the rules in 42 CFR 410 and the Medicare Benefit Policy Manual, chapter 15, section 80.6.1 require that tests must be ordered by the physician who is treating the beneficiary.[4] A treating physician, as defined in Section 1861(r)(1) of the Social Security Act, is a physician "who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary's specific medical problem."[5] Palmetto considers a treating physician as any physician who is actively part of a team that manages a patient's care. Further, Palmetto has stated it considers pathologists part of the treating team because they help determine the appropriate molecular test to use. In addition, the Medicare Benefit Policy Manual Chapter 15, section 80.6.5, includes a "Surgical/Cytopathology Exception" which 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.[6]

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 immediately from the coverage policy and that CMS work with its MACs to ensure local coverage policies do not improperly limit the scope or define the practice of medicine by board-certified pathologists. Such limiting criteria ignores the extensive training and competencies of board-certified physicians and sets a dangerous precedent with the potential to severely limit access to necessary care for Medicare patients.
If you have any questions or would like additional information that would be helpful please contact Annie Scrimenti, Associate Director, Public Policy & Advocacy, AScrimenti@amp.org at 301-634-7932, or Nonda Wilson, Manager, Economic and Regulatory Affairs, nwilson@cap.org at 202-354-7116.

Sincerely,

Association for Molecular Pathology
College of American Pathologists

References

1. Palmetto GBA local coverage determination; MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma (L39345). Available from: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39345&ver=3&lcdStatus=A&sortBy=title&bc=6

2. Medicare Act, 42 U.S.C. §1395.

3. Social Security Act, section 1862(a)(1)(A).

4. 42 CFR §410.32; *see also* Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services. *Medicare Benefit Policy Manual*. Pub. No. 100-02, chapter 15, §80.6.1. Available from: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf

5. Social Security Act, section 1861(r)(1).

6. Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services. *Medicare Benefit Policy Manual*. Pub. No. 100-02, chapter 15, §80.6.5. Available from: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf