



August 5, 2022

Palmetto GBA
MoIDX Policy
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RE: MoIDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma (DL39345)

Dear Dr. Bien-Willner,

On behalf of the Association for Molecular Pathology (AMP) and the College of American Pathologists (CAP), we thank you for the opportunity to review and comment on the proposed MoIDX policy Molecular Assays for the Diagnosis of Cutaneous Melanoma (DL39345)

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. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry.

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. We are submitting a joint comment letter because our organizations share the same position regarding this draft LCD.

After reviewing the proposed policy, we ask that Palmetto consider the following recommendation in the final coverage policy:

The proposed LCD states that molecular assays for diagnosing cutaneous melanoma are to assist **dermatopathologists** in arriving at the correct diagnosis of melanoma versus non-melanoma lesions when examining skin biopsies. The LCD further states that to receive coverage the test must be ordered by a board-certified or board-eligible **dermatopathologist**. We are deeply concerned that such limiting criteria set a dangerous precedent which will severely limit access to necessary testing for Medicare patients. 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. **We strongly urge Palmetto not to limit its criterion for test ordering to dermatopathologists only but rather to expand it to include board certified anatomic pathologists.**

The Summary of Evidence section of the proposed LCD references gene expression profile assays myPath® Melanoma and DecisionDX® DiffDX™, both proprietary tests. Consistent with our standard practice of not commenting on sole-source or proprietary tests, we will not comment further on the LCD at this time, but should additional tests qualify for coverage under this policy in the future the AMP and CAP will assess this information and may offer additional comments at that time.

Thank you again for the opportunity to review and comment on this proposed policy. As always, AMP and CAP welcome the opportunity to work collaboratively with Palmetto in its efforts to improve the quality of care provided to patients within its jurisdictions. Please direct any questions or comments regarding this correspondence to Sarah Thibault-Sennett, AMP Director Public Policy & Advocacy, at SThibaultSennett@amp.org or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at nwilson@cap.org.

Sincerely,

Association for Molecular Pathology
College of American Pathologists