



# COLLEGE of AMERICAN PATHOLOGISTS

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October 12, 2023

MolDX Policy  
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RE: MolDX: Molecular Testing for Risk Stratification of Thyroid Nodules (DL39646)

Dear Dr. Bien-Willner,

Thank you for the opportunity to review and comment on Palmetto's proposed coverage policy for Molecular Testing for Risk Stratification of Thyroid Nodules (DL39646). As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

As a general matter, the CAP supports Palmetto's proposed coverage policy for molecular diagnostic testing to evaluate indeterminate or suspicious thyroid nodules. Providing the most accurate assessment of malignancy risk is critical for determining appropriate treatment and preventing unnecessary surgery. However, we request Palmetto consider the following clarification or addition to the final LCD to ensure that additional molecular testing will be covered for patients with multiple concurrent indeterminate nodules or who develop a new, changing or clinically concerning nodule over time.

## Coverage Indications, Limitations, and/or Medical Necessity

Currently, the draft LCD states that Palmetto "will cover molecular diagnostic tests for use in a beneficiary with an indeterminate or suspicious thyroid nodule" when all the following criteria are met:

- The patient:
  - Has not been tested with the same or similar assay for the same clinical indication AND:
    - Has an indeterminate thyroid nodule as defined by Bethesda categories III-I OR
    - Has a Bethesda category V nodule for which molecular testing may aid in further stratifying the type of malignancy.

CAP Comment: The bullet above limits coverage to patients who have not been tested with the same or similar assay for the "same clinical indication." Yet, patients with multiple concurrent indeterminate nodules or who develop new nodules over time require repeat



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evaluation. Further, given the long-term follow up time frames for patients, nodules can accumulate additional potentially oncogenic mutations over time, thus it is possible that even the same nodule may require retesting. **Therefore we request that the final LCD clarify that additional molecular testing be covered for patients with multiple concurrent indeterminate nodules or who develop a new, changing or clinically concerning nodule over time.**

As pathologists, we know that the right test at the right time can make all the difference in a patient's diagnosis, treatment, and outcome. We appreciate your consideration of our request to ensure that Medicare patients have access to appropriate testing.

Thank you again for the opportunity to review and comment on this proposed policy. Should you have additional questions or require our expertise, please direct your correspondence to Nonda Wilson, CAP's Manager of Economic and Regulatory Affairs, at [nwilson@cap.org](mailto:nwilson@cap.org).

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