ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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October 11, 2025

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Submitted electronically via policycomments@wpsic.com

Subject: MolDX: Genetic Testing for Hereditary Thrombophilia (DL40274)

Dear Dr. Nachodsky,

On behalf of the Association for Molecular Pathology (AMP), we thank you for the opportunity to comment on the draft Local Coverage Determination (dLCD) entitled MolDX: Genetic Testing for Hereditary Thrombophilia.

AMP is an international medical and professional association representing approximately 3,100 physicians, doctoral scientists, and medical laboratory scientists (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. AMP members are highly involved in the development, validation, and interpretation of molecular diagnostic tests, including hereditary thrombophilia testing.

Coverage Indications, Limitations, and/or Medical Necessity

AMP greatly appreciates WPS generally proposing favorable coverage of hereditary thrombophilia testing; however, the Criteria for Coverage omits important clinical scenarios in which testing is both reasonable and necessary for the management of venous thromboembolism (VTE). The American Society for Hematology (ASH) has developed robust, evidence-based guidelines outlining when thrombophilia testing is warranted, and AMP requests that the WPS revise the dLCD to include all of the testing recommendations from ASH.[1] Specifically, the final LCD should provide coverage for

[1] Middeldorp S, Nieuwlaat R, Baumann Kreuziger L, Coppens M, Houghton D, James AH, Lang E, Moll S, Myers T, Bhatt M, Chai-Adisaksopha C, Colunga-Lozano LE, Karam SG, Zhang Y, Wiercioch W, Schünemann HJ, Iorio A. American Society of Hematology 2023 guidelines for management of venous thromboembolism: thrombophilia testing. Blood Adv. 2023 Nov 28;7(22):7101-7138. doi: 10.1182/bloodadvances.2023010177. PMID: 37195076; PMCID: PMC10709681.

thrombophilia testing in direct alignment with Table 1, which states that testing should be provided for a number of clinical situations, the situations stated below are the only other ones applicable to the Medicare population.

The Final LCD Should Establish:

Coverage for Asymptomatic Individuals with Family History of VTE

AMP recommends incorporating language into the policy to support testing access for patients with additional VTE risk factors and a known hereditary predisposition. AMP strongly recommends coverage for asymptomatic individuals with a family history of VTE and/or hereditary thrombophilia. In alignment with the ASH guidelines, we urge WPS to revise Criterion 1 to explicitly allow coverage for thrombophilia testing in asymptomatic individuals—particularly those with protein C, protein S, or antithrombin deficiencies. Additionally, AMP supports testing individuals with a family history of VTE who are considering Hormone Replacement Therapy.

Testing Access for Cancer Patients with Family History of VTE

AMP also recommends expanding coverage to include patients with cancer who are at low or intermediate risk for VTE but have a first-degree relative with a history of VTE. Family history in these cases represents a clinically meaningful risk factor, and access to testing should not be restricted.

The LCD Should Focus on Clinical Utility Criteria for Coverage

Criterion 4 states that a test should not include additional genetic content that has not been properly validated or has unclear clinical validity. AMP is strongly committed to ensuring that all molecular tests are high-quality, properly validated, clinically appropriate, and meaningfully contribute to patient care. We understand that the MolDX program requires a technical assessment, which is addressed in Criterion 6. We believe that aspects of Criterion 4 are duplication with other federal requirements including those established via the Clinical Laboratory Improvement Amendment program [2] Because questions about validation are addressed via the technical assessment process and through other regulatory programs, we respectfully request the removal of Criterion 4 from the dLCD.

Thank you again for the opportunity to review and comment on this draft policy. We are happy to provide additional clinical or other information to assist you as you work towards finalizing the LCD. Please direct your correspondence to Annie Scrimenti, Director of Public Policy and Advocacy, at ascrimenti@amp.org.

Sincerely,
Jane S. Gibson, PhD
President, Association for Molecular Pathology

[2] eCFR :: 42 CFR Part 493 -- Laboratory Requirements