ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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Submitted electronically via policycomments@wpsic.com

Subject: MolDX: Biomarker Testing for Risk Stratification in Metabolic Dysfunction-Associated Steatotic Liver Disease and Metabolic Dysfunction-Associated Steatohepatitis (DL40272)

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: Biomarker Testing for Risk Stratification in Metabolic Dysfunction-Associated Steatotic Liver Disease and Metabolic Dysfunction-Associated Steatohepatitis.

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 biomarker tests for the diagnosis and management of liver fibrosis in the setting of metabolic dysfunction-associated steatotic liver disease (MASLD) and metabolic dysfunction-associated steatohepatitis (MASH).

AMP greatly appreciates tha WPS is proposing to generally cover biomarker testing for assessing the risk of liver fibrosis in the setting of MASLD or MASH, when certain conditions are met. We have identified several changes, outlined in the information below, that we believe will help streamline the policy and ensure that patients have timely access to this essential testing.

Coverage Indications, Limitations, and/or Medical Necessity

Removal of Ambiguous Language Regarding Test Compliance

AMP strongly urges WPS to remove the following sentence from Criterion 9:

"*New tests that become available with significantly improved performance may render older tests no longer compliant with this policy."*

This statement is subjective and lacks any measurable criteria for determining coverage. Without clear standards for what constitutes significantly improved performance for new tests as compared to long-established tests, it risks creating uncertainty for laboratories, clinicians, and patients . Given the rapid pace of innovation in biomarker testing, maintaining ambiguous language of this kind will undermine predictability in coverage decisions, discourage continued use of clinically validated tests, and ultimately disrupt patient access to medically necessary testing. Instead, AMP recommends that any future coverage changes be based on explicit, evidence-based criteria developed through a transparent process.

Allow More Flexibility in Testing

AMP is concerned that Criterion 5, which restricts testing within 12 months following a liver biopsy, is too restrictive. Thus, AMP recommends that Criterion 5 reads as follows:

"Testing is not performed more than once within a 12-month period nor within 12 months following a liver biopsy testing biopsy with successful fatty liver disease scoring by a pathologist."

An unsuccessful fatty liver disease scoring leads to diagnostic ambiguity and will compromise patient care if there is no repeat scoring within the 12-month period mentioned in the criterion 5. This revision balances appropriate safeguards on testing with clinical flexibility, ensuring patients receive necessary testing for accurate risk stratification in MASLD or MASH testing

Remove Redundant Criteria

AMP recommends removing Criteria 6 and 7, as their content is duplicative of the requirements already outlined in the technical assessment process. The focus of the coverage criteria should be on outlining coverage and medical necessity for testing, not repeating standards addressed within the technical assessment.

Additionally, if WPS chooses to maintain Criterion 6, we strongly urge you to revise the following sentence:

"Clinical validity (CV) of any analytes or profiles must be established through a study published in the peer-reviewed literature for the intended use of the test in the intended population with demonstrated reproducibility across clinical study cohorts."

The current language could be misinterpreted to mean that each laboratory must independently publish clinical studies for tests already supported by published evidence. We recommend clarifying that laboratories are not required to generate or publish their own CV data if such evidence already exists in the literature. If Criteria 6 and 7 remain in the LCD, we urge consistent language across all LCDs, ensuring that these criteria do not impose requirements more stringent than those found in existing technical assessment forms.

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