ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852
Tel: 301-634-7987 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

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Denise Nachodsky, M.D.
1717 W. Broadway
PO Box 1787
Madison, WI 53701-1787

Submitted electronically via policycomments@wpsic.com

Subject: DL40472 MolDX: Next-Generation Sequencing for Hematologic Malignancies and Suspected Hematologic Malignancies

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 DL40472 MolDX: Next-Generation Sequencing for Hematologic Malignancies and Suspected Hematologic Malignancies

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, particularly in hematologic neoplasms.

AMP strongly agrees with the proposed LCD's expanded coverage of next-generation sequencing (NGS) testing for hematologic malignancies, inclusive of myeloid and lymphoid neoplasms, when previously only myeloid neoplasms were covered. The new language addresses a critical gap in coverage, allowing patients to access comprehensive hematologic malignancy testing as needed. However, we have some concerns and suggestions for inclusion within the dLCD, specifically under the coverage criterion.

Revise Criterion 1 to reflect genetic understanding of disease

AMP has concerns about parenthetical in Criterion 1. While we understand the intent of the parenthetical, which recognizes that disease progression and transformation are associated with clonal evolution and/or new genetic alterations not detected by prior testing. However, the phrase "representing an a priori change in genetic content" may be misinterpreted as a qualifying condition, requiring documentation that a genetic change has occurred before testing is covered. Only the test itself can establish whether such a change has occurred. Replacing "representing an a priori" with "presumed to reflect" preserves the intended meaning while removing the potential for a restrictive reading during claims review. **AMP requests that WPSIC change Criterion 1 to read:** *a confirmed*

hematologic malignancy in accordance with current national or international consensus diagnostic guidelines (i.e., International Consensus Classification of Myeloid and Lymphoid Neoplasms (ICC); the World Health Organization Classification of Haematolymphoid Tumours (WHO)), and is undergoing evaluation at the time of initial diagnosis; prior to initiation of first or subsequent lines of therapy; disease progression/transformation (presumed to reflect a ~~representing a priori~~ change in genetic content), including progression on targeted therapy*; clinical relapse; primary refractory disease or loss of response; or evaluation for stem cell transplantation OR"*

Make edits to reflect key national or international consensus diagnostic/clinical practice guidelines

AMP appreciates the inclusion of International Consensus Classification of Myeloid and Lymphoid Neoplasms (ICC), the World Health Organization Classification of Haematolymphoid Tumours (WHO), and the National Comprehensive Cancer Network (NCCN). **As the American Society of Hematology's guidelines align with the guidelines listed, in order to have complete coverage of guidelines surrounding Hematologic malignancies, AMP suggests the addition of the Clinical Practice Guidelines on Acute Myeloid Leukemia in Older Adults published by the ASH.**

AMP would also like to note that there are language changes recently published in the NCCN guidelines as a result of their work to standardize biomarker language. Specifically, the term "molecular profiling" does not exist in some updated guidelines. Instead, it has been replaced by the term "multigene panel testing (MGPT)" in many of the applicable guidelines for this coverage document.[1][2] **AMP requests WPSIC clarify within the coverage policy that this terminology discordance exists and add the term "multigene panel testing" to the definitions available in the LCD.**

Remove medical documentation requirement

Overall, AMP agrees with the information included in criteria 1a and 1b. **AMP requests the addition of the following language (in red) to criterion 1b.**

> *an undiagnosed but highly suspected hematologic malignancy in accordance with current national or international consensus guidelines (as above), AND a standard evaluation to rule out benign or reactive causes (e.g., infectious, inflammatory etiology) has been performed. ~~as documented in the medical record~~*

AMP is concerned that requiring laboratories to submit medical record documentation to obtain coverage for a laboratory test places an unreasonable and inequitable burden on laboratories. In many cases, laboratories receive only the test requisition form (TRF) from the ordering provider and do not have access to the patient's complete medical record. Moreover, interoperability limitations between hospitals, providers, and laboratories may prevent laboratories from obtaining the documentation required for billing. Laboratories should not be denied payment or otherwise penalized for failing to provide documentation that is outside their control or not reasonably accessible to them.

Add "risk stratification" as a need for molecular profiling

[1] https://www.nccn.org/professionals/physician_gls/pdf/all.pdf

[2] https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf

Current clinical research and guidelines show that risk stratification is incredibly important in testing for hematologic malignancies.[3,4,5] The ability to have precise prognosis, tailored therapies, and continued monitoring is integral for patients to access the treatment they need. **As a result, AMP suggests the following addition below (in red) to Criterion 2b.**

Molecular profiling is necessary to direct immediate clinical management, inclusive of targeted therapy selection, decisions regarding treatment intensity, risk stratification, or determination of hematopoietic stem cell transplantation eligibility, as established by national clinical practice guidelines (such as those from the National Comprehensive Cancer Network (NCCN)), and has not yet been established by other non-NGS testing.

Clarify terms to allow for complementary testing

AMP would like clarity on the definition of "same or similar genetic content" as written in criterion 3. There is complementary testing such as FISH and karyotyping that can provide additional information about the patient's hematological malignancy. These tests should not be considered duplicative as they provide different clinical information. **AMP requests that the coverage policy specify that complementary testing is not considered the "same or similar genetic content."**

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 Samantha Pettersen Policy Manager, Public Policy and Advocacy at spettersen@amp.org.

Sincerely,

Jay Patel, MD
Chair, Economic Affairs Committee
Association for Molecular Pathology

[3] https://pmc.ncbi.nlm.nih.gov/articles/PMC9214472/
[4] https://www.nccn.org/professionals/physician_gls/pdf/all.pdf
[5] https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf