



ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
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Barry Whites M.D., FCCP, MSHA, CHCQM
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Barry Whites M.D., FCCP, MSHA, CHCQM

Re: MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer - DL38684

Dear Dr. Whites,

On behalf of the Association for Molecular Pathology (AMP), we thank you for the opportunity to review and comment on the proposed policy for MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer (DL38684).

AMP is an international medical and professional association representing approximately 2,600 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 commented on the previous version of this proposed policy in June 2020, and we plan to share similar comments in this letter. We appreciate your approach to proposing coverage for tests that demonstrate valuable information when used to make significant clinical decisions for cancer patients, rather than providing recommendations regarding the use of a specific drug or treatment. The policy parameters support coverage for the care needed to help manage bladder cancer patients and this approach to coverage will facilitate the development of better tests for bladder cancer and other tumors by accelerating their market introduction and reducing clinical uncertainty.

After reviewing the proposed policy's coverage criteria, we ask that you consider the following recommendations.

Coverage Indications, Limitations, and/or Medical Necessity

1. Coverage criteria #2 states the following:

The beneficiary is within the population and has the indication for which the test was developed and is covered. The lab providing the test is responsible for clearly indicating to treating clinicians the population and indication for test use.

AMP is concerned about the requirement for laboratories to verify that a patient meets a policy's coverage criteria. Laboratories do not keep patient medical records, nor do they always have access to them. The treating physician, and not the laboratory, must take responsibility for the medical necessity of a test because only the treating physician, not the laboratory, will have the necessary information to make that

determination. For this reason, it would not be reasonable to hold the laboratory responsible for substantiating the medical necessity of a test. This is especially pertinent as there are many tests for which there is no FDA-approved alternative, and under Clinical Laboratory Improvement Amendments (CLIA), it is the laboratory's responsibility to only document the validity of the test for the analyte it purports to assay.

For these reasons, we recommend you remove the last sentence in coverage criteria #2 which makes laboratories responsible for the appropriate beneficiary population and indications for test usage by treating clinicians.

The beneficiary is within the population and has the indication for which the test was developed and is covered. ~~The lab providing the test is responsible for clearly indicating to treating clinicians the population and indication for test use.~~

Alternatively, if you do not wish to strike the last sentence, as indicated above, we recommend the proposed language be revised as follows: "The laboratory will make available the appropriate indications of the test to the ordering physician."

2. Coverage criteria #6 states the following:

The test successfully completes a Molecular Diagnostic Services Program (MoIDX®) technical assessment that ensures the test is reasonable and necessary as described in 4. and 5. above.

The Molecular Diagnostic Services Program (MoIDX®) Technical Assessment (TA) has been a well-established requirement of the MoIDX® program since 2011. Since that time, laboratory developed tests or tests with undefined or unproven clinical utility have had to undergo a TA to ensure coverage. The TA process is detailed on your website and is a coverage requirement that applies to all molecular diagnostic tests covered under MoIDX® and, therefore, does not need to be reiterated in individual LCDs. Accordingly, AMP recommends removing the requirement that a test must successfully complete a TA, as it is redundant and unnecessary.

Thank you again for the opportunity to review and comment on this proposed policy. We are happy to be of assistance in providing additional clinical or other information to assist you with this draft LCD. Please direct your correspondence to either Sarah Thibault-Sennett, AMP's Director of Public Policy & Advocacy, at sthibaultsennett@amp.org.

Sincerely,

Samuel K. Caughron, MD Chair, Economic Affairs
Committee Association for Molecular Pathology