June 12, 2020

Meredith Loveless, MD
2 Vantage Way
Nashville, TN 37228
cmd.inquiry@cgsadmin.com

RE: MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer DL38586

Dear Dr. Loveless,

On behalf of the Association for Molecular Pathology (AMP) and the College of American Pathologists (CAP), we thank you for the opportunity to review and comment on the proposed policy for MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer DL38586.

The AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical 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.

The CAP is the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs. The CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

We are submitting joint comments because currently our organizations share the same position regard this draft LCD.

Both AMP and CAP appreciate CGS' 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 use of a specific drug or treatment. The policy parameters support coverage needed to help manage bladder cancer patients and this approach to coverage will help to facilitate the development of better tests in the future 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 CGS consider the following recommendations.

Coverage Indications, Limitations, and/or Medical Necessity

1. The second coverage criteria (#2) requires that "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."

The AMP and CAP are concerned about Laboratories being held responsible for verifying that a patient meets a coverage policy's 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 CLIA, it is the laboratory's responsibility to only document the validity of the test for the analyte it purports to assay.

Recommend: We recommend CGS remove the last sentence in criteria #2 making labs responsible for the appropriate beneficiary population and indications for test usage by treating clinicians, for the aforementioned reasons. **Alternatively**, amend the proposed policy language to state that the lab will make available the appropriate indications of the test to the ordering physician.

2. Number seven (#7) of the coverage criteria states that a test must successfully complete a technical assessment that will ensure that analytical and clinical validity criteria are met to establish the test as reasonable and necessary. The Molecular Diagnostic Services (MolDX) Technical Assessment (TA) has been a well-established requirement of the MolDX program since 2011. Since that time, laboratory developed tests or test with undefined or unproven clinical utility have had to undergo a TA to ensure coverage. The TA process is detailed on the CGS website and is a coverage requirement that applies to all molecular diagnostic tests covered under MolDX, and therefore, does not need to be reiterated in individual LCDs.

Recommend: Remove 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 Tara Burke, Director of Public Policy, at tburke@amp.org or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at nwilson@cap.org

Sincerely,

Association for Molecular Pathology
College of America Pathologists