ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
6120 Executive Blvd., Suite 700, Rockville, MD 20852
Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

November 15, 2020

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Proposed Decision Memo for Screening for Colorectal Cancer Blood-Based Biomarker Tests (CAG-00454N)

Dear Ms. Syrek Jensen:

The Association for Molecular Pathology (AMP) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed decision memo for screening for colorectal cancer blood-based biomarker tests. 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.

AMP commends CMS for providing a proactive coverage standard that recognizes the value of blood-based biomarker tests as another non-invasive option for the early detection of colorectal cancer. This is an evolving area of medicine and having an established pathway to national coverage will expand patient access to medically-appropriate screening tests as they are introduced clinically. Additionally, many Medicare beneficiaries fail to comply with recommendations for colorectal cancer screening and providing more methods for individuals to be screened will likely help increase access, adherence, and earlier detection of colorectal cancer.

While we are appreciative of this coverage standard, we do have some concerns regarding the proposed coverage policy and its implications for future coverage policies. As such, AMP would like to provide comments on the following proposed coverage criteria:

- FDA market authorization with an indication of colorectal cancer screening;
- Proven test performance characteristics for a blood based screening test with both sensitivity greater than or equal to 74% and specificity greater than or equal to 90% in the detection of colorectal cancer compared to the recognized standard (accepted as colonoscopy at this time), based on the pivotal studies included in the FDA labeling; and
- Inclusion as a recommended routine colorectal screening test in at least one professional society guideline or consensus statement or USPSTF recommendation.

1. ***FDA market authorization with an indication of colorectal cancer screening***

Requiring FDA market authorization unreasonably narrows patient access to clinically useful blood-based colorectal cancer screening tests, and as drafted, this policy eliminates any possible path for tests without FDA authorization; it states that "all other indications for colorectal cancer screening not otherwise specified in the ACT and regulations, or otherwise specified above remain nationally non-covered." Blood-based biomarker screening tests are a growing and dynamic type of testing. **To ensure that clinically and analytically-validated colorectal screening tests are recognized by Medicare as a viable, covered service for beneficiaries, CMS should provide coverage pathways within the NCD for other tests, such as those performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, in addition to those tests that voluntarily seek authorization by the Food and Drug Administration (FDA).**

Both the CMS Coverage and Analysis Group and the Department of Health and Human Services (HHS) have existing policies that support coverage pathways for laboratory developed testing procedures and clarification that such tests do not require FDA authorization. First, the National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2) provides coverage pathways for both FDA-approved or –cleared tests as well as laboratory developed testing procedures, the latter via promulgation by Medicare Administrative Contractors (MACs)[1]. Secondly, after review by the Office of the General Counsel this year, HHS "determined that the Food and Drug Administration ("FDA") will not require premarket review of laboratory developed tests ("LDT") absent notice-and-comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances."[2] This rescission of guidance documents and other informal policy specifically states that laboratory developed testing procedures will remain subject to regulation by CMS CLIA, which assures laboratory performance standards and laboratory developed testing procedures' accuracy, validity, and reliability. Therefore, mandating FDA authorization for laboratory developed testing procedures as a prerequisite to receiving national coverage under Medicare is incongruent with and unnecessary under current HHS policy. We ask that the NCD be modified to be consistent with current regulatory policy within HHS.

2. ***Proven test performance characteristics for a blood based screening test with both sensitivity greater than or equal to 74% and specificity greater than or equal to 90% in the detection of colorectal cancer compared to the recognized standard (accepted as colonoscopy at this time), based on the pivotal studies included in the FDA labeling***

AMP has significant concerns with CMS dictating sensitivity and specificity requirements in any coverage policy and believes it is not the role of the Coverage and Analysis Group at CMS to evaluate tests' sensitivity and specificity requirements in order to determine a test's medical usefulness. Diagnostic performance, such as test sensitivity and specificity, should be determined by FDA in the event the test is an in vitro diagnostic test kit, or under the CLIA program if the test is a laboratory developed testing procedure. **The Coverage and Analysis Group dictating performance standards is outside its mandate to evaluate the clinical utility of a service and even more concerning, staff lack the scientific expertise to establish performance characteristics. This should be left to agencies and divisions with those oversight authorities, i.e. FDA and the CLIA Program. Moreover,**

[1] https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=372
[2] https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html

we believe this criterion sets a dangerous precedent for future coverage policies. For these reasons, we strongly recommend deletion of this criterion. AMP welcomes the opportunity to discuss this issue and our concerns further with CMS.

3. ***Inclusion as recommended routine colorectal screening test in at least one professional society guideline or consensus statement or USPSTF recommendation***

We are pleased to see these guidelines recognized as a criterion for coverage in this policy**. AMP strongly supports this coverage criterion and specifically, the inclusion of a recommended routine colorectal screening test in at least one professional society guideline or consensus statement.** AMP continues to believe that coverage policies should align with evidence-based guidelines written by professional medical societies. When guidelines support the utility of a test, they also support coverage for that test. For example, specific to this coverage policy, the current National Comprehensive Cancer Network guidelines for Colorectal Cancer Screening acknowledge that blood-based screening tests for colorectal cancer are an emerging testing option.[3]

AMP also invests in a robust program to leverage the field's expertise to develop Clinical Practice Guidelines and Reports, which assist laboratory and other health care professionals by providing guidance and recommendations for particular areas of practice. The AMP Clinical Practice Guidelines Program is comprised of multiple AMP-led working groups that plan, organize and coordinate efforts such as practice guidelines, sample exchanges, reporting surveys, validation and quality control measures. The majority of these projects include representation from other professional organizations and groups. AMP's Clinical Practice Guidelines Program as well as other efforts from additional organizations such as the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), American College of Genetics and Genomics (ACMG), and the College of American Pathologists (CAP) are key to establishing parameters for clinical practice.

Thank you again for the opportunity to review and provide comments on this proposed decision memo. AMP appreciates CMS' efforts to ensure access to medically necessary testing and provide coverage for testing more broadly. We welcome the opportunity to work with you and should you have any questions or require additional information, please direct your correspondence to Tara Burke, Senior Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Karen E. Weck, MD FCAP
President, Association for Molecular Pathology

[3] https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf