



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

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June 24, 2021

The Honorable Mike Crapo
U.S. Senate
239 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Michael Bennet
U.S. Senate
261 Russell Senate Office Building
Washington, DC 20510

Delivered electronically

Dear Senator Crapo and Senator Bennet:

The Association for Molecular Pathology (AMP) is pleased to see the introduction of S. 1873, the Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021 (MCSA). 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 the government, academic, private, and hospital-based clinical laboratories, and the in-vitro diagnostics industry.

Currently, Medicare's coverage for early cancer detection has been limited to five cancers – breast, cervical, colorectal, lung, and prostate cancer – each detected via an individual test. Recent advances in the molecular and genetic understanding of cancer have led to the development of innovative diagnostic tests that can screen for multiple types of cancer at the same time. With the anticipated change in the standard of care for cancer screening practice, the MCSA will help ensure that coverage policy is consistent with these new approaches by authorizing the Centers for Medicare and Medicaid Services (CMS) to expand Medicare coverage for multi-cancer screening tests, including blood-based tests for the early detection of multiple cancer types.

Early detection of a wide range of cancers is critical because there are deadly cancers such as pancreatic and liver cancer with less than a 5% survival rate when it has metastasized.¹ AMP believes that providing Medicare coverage for innovative multi-cancer screening tests will improve cancer patients' care and save lives by increasingly the likelihood that cancer is detected early before it has spread. The bill is an important first step to expand Medicare coverage of screening for multiple cancers simultaneously, reflecting recent innovation and advancements in laboratory medicine. Thank you for recognizing the need to modernize coverage policy and working to ensure that Medicare beneficiaries have access to such potentially life-changing tests.

However, AMP is concerned with a specific provision in the bill that will limit this coverage to only screening tests with a Food and Drug Administration (FDA) authorization, likely creating unnecessary barriers to cancer screening. While we greatly support the bill's aim to enable patients' access to these tests, restricting coverage to tests with FDA approval or clearance will limit patient access to multi-cancer screening tests. Related laws on

¹ <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf>

Medicare coverage of preventive services for cancer screening do not reference any regulatory requirement for coverage. The sections specific to preventive services in the Social Security Act (42 U.S.C. 1395l(a)(1)(Y)) for breast, prostate, cervical, and colorectal cancer use generic descriptions for the screening tests allowed, e.g., mammography, colonoscopy, pap smear, and do not refer to their regulatory status. Technology changes over time and if a statute is too prescriptive, then CMS won't have the flexibility to adapt its coverage policy over time. AMP believes it is best that the Agency maintain this flexibility when setting policy for multi-cancer screening tests. Historically, once CMS was granted authority to cover screening tests in statute, the Agency has used its national coverage determination process or other regulatory mechanisms to establish specific criteria for coverage. Moreover, the provision requiring FDA authorization is not consistent with current regulatory policy. In addition to in vitro diagnostic tests authorized by FDA, clinical laboratories and the laboratory developed testing procedures that they develop and perform are regulated by CMS under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), in addition to state level requirements, and professional accreditation bodies. Hence, current regulatory policy means that test developers of cancer screening tests are in full regulatory compliance without seeking premarket review by FDA.

For these reasons, AMP believes that limiting coverage to screening tests with FDA approval or clearance could unintentionally restrict patients' access to these tests, and respectfully request that the language be modified before advancing the legislation. AMP suggests this redlined edit in Section 3 of the bill, and of course, is open to suggestions from your office:

“(III) Multi-Cancer Early Detection Screening Tests.—The term ‘multi-cancer early detection screening test’ means any of the following tests, ~~approved or cleared by the Food and Drug Administration~~, furnished to an individual for the purpose of early detection of cancer across many cancer types (as categorized in the Annual Report to the Nation on the Status of Cancer issued by the National Cancer Institute):

“(1) A genomic sequencing blood or blood product test that includes the analysis of cell-free nucleic acids.

“(2) Such other equivalent tests (which are based on urine or other sample of biological material) as the Secretary determines appropriate.”

AMP reiterates our support in expanding Medicare coverage for multi-cancer screening tests; however, we believe that language changes are needed to ensure statute does not unintentionally create barriers for Medicare beneficiaries wishing to access screening for cancer. Our members appreciate the opportunity to provide feedback and recommendations on the legislation. We look forward to working with Congress to ensure that MCSA is modified to best ensure that cancer patients can access important screening tests such as multi-cancer screening tests that can save lives without creating unnecessary obstacles to cancer screening.

Sincerely,

Antonia R. Sepulveda, MD, PhD
President, Association for Molecular Pathology