ACS CAN Supports the *Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Act* (H.R. 2407)

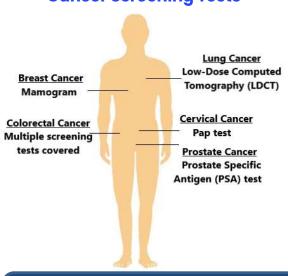


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Multi-Cancer Screening Tests Can Catch Cancer Early

Earlier screening for cancer is important because when detected at later stages, treatments are more limited, and outcomes are generally poorer. Medicare enrollees should have access to multi-cancer screening tests when the benefit is clinically shown. Multi-cancer early detection tests are innovative tests that have the potential to detect multiple cancers through the use of a single test. Several private and academic entities are currently developing multi-cancer early detection blood-based tests. Published data indicate that some of these tests can screen for many different types of cancers at the same time, including some rare cancers.

Current Medicare Coverage of Cancer Screening Tests



Multi-Cancer Screening Tests
1 Test: Multiple Cancers Screened

Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening

Coverage Act Would Enhance Medicare Screening

Because the risk of cancer increases with age, Medicare beneficiaries are especially vulnerable. The Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act (MCED) would potentially expand access to cancer screenings in Medicare. The legislation would grant Medicare the authority to cover multi-cancer early detection tests, once the test has been approved by the Food and Drug Administration (FDA) and clinical benefit is shown. The Centers for Medicare & Medicaid Services (CMS) will determine its coverage parameters (subject to the revised language) through an evidence-based process.

The bill makes clear that Medicare's coverage of MCED tests does not affect Medicare's coverage of other screening modalities. Coverage of these new tests will complement – not replace – Medicare's existing coverage of cancer screening tests. The bill will provide CMS the authority to create coverage parameters but does not mandate that CMS cover specific tests. Without legislation, Medicare beneficiaries could experience unacceptable delays in access to multi-cancer early detection.



A Phased-In Approach

The legislation has been revised to include the following policies:

- Implementation date: The revised legislation makes clear that CMS may not begin coverage of MCED tests until 2028. This change aligns with an anticipated timeline for FDA approval of MCEDs.
- Phase-in eligibility: The revised legislation phases in coverage of MCED tests. All evidence-based cancer screenings have an age criterion. Beginning as early as January 1, 2028, Medicare could provide coverage of MCED tests for individuals who are 67 years old and younger. For each subsequent year Medicare coverage would increase by one year. For example, in the year 2029 Medicare could cover MCED tests for individuals who are 68 years old and younger.
- Payment rate: The revised legislation would initially set the Medicare payment rate for MCED tests to the payment rate for multi-target stool DNA tests in place on the date of enactment of the legislation. After 2031, the legislation would set the payment amount to the lesser of the payment rate for the multi-target stool DNA tests in place on the date of enactment or the current payment rate for that test.

Multi-Cancer Early Detection Screening Could Help Reduce Cancer Disparities

Overall cancer mortality rates have been declining for more than two decades in the United States, but racial, socio-economic and geographic disparities persist. The availability of multi-cancer screening tests has the potential to address cancer mortality disparities by detecting more cancers earlier in more people.

Cancer disparities occur mostly because of barriers to high quality cancer prevention, early detection, and treatment due to inequities in employment, wealth, education, housing, and standards of living. For example, approximately 20% of Medicare beneficiaries live in rural areas and residents of rural areas have lower rates of cancer screenings for services like lung cancer for which specialized equipment is needed. A simple blood test may be more accessible and acceptable to patients, thereby extending screening opportunities to traditionally underserved communities. Reducing cancer disparities can only be achieved if there is equitable access to the test in underserved communities, which Medicare coverage can help promote.

June 26, 2024

The legislative changes are included in the Ways and Means Committee's Amendment in the Nature of a Substitute to HR 2407, the "Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act." Legislative language is available