The Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act (H.R. 842/S. 339)

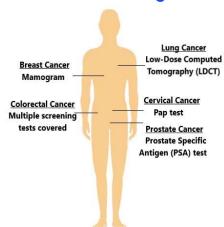


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Multi-Cancer Screening Tests Can Catch Cancer Early

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 (MCED) 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

The 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)* (H.R. 842/S. 339) would potentially expand access to cancer screenings in Medicare. The legislation would grant Medicare the authority to cover multi-cancer early detection (MCED) tests, once the test has been approved by the FDA and clinical benefit is shown. CMS will determine its coverage parameters 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 – and 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.

This bipartisan and bicameral legislation was the most supported health care bill in the 118th Congress with the broad support of 320 members of the House of Representatives and 65 members of the Senate.

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A Phased-In Approach

In order to ensure the legislation provides the greatest benefit to the those who are most likely to benefit, and to ensure the legislation falls within certain budget parameters, the legislation includes the following policies:

- Implementation date: The 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 68 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 legislation would set the Medicare payment rate for MCED tests. For tests furnished before Jan. 1, 2031, the payment amount is equal to the payment for multi-target stool screening DNA test

Age Phase-in		
Year	Who IS covered	Who is NOT covered
2028	68 years old and younger	69 years old and older
2029	69 years old and younger	70 years old and older
2030	70 years old and younger	71 years old and older
2031	71 years old and younger	72 years old and older
2032	72 years old and younger	73 years old and older
2033	73 years old and younger	74 years old and older
2034	74 years old and younger	75 years old and older
2035	75 years old and younger	76 years old and older
Upper age limit keeps increasing by one year		

(Cologuard test) in place on date of enactment of the legislation. Tests furnished after Jan. 1, 2031, the payment amount is equal to the lesser of the payment amount of the stool-based DNA test on the date of enactment or the current payment amount 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.

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