

ACS CAN Supports the *Nancy Gardner Sewell Medicare Multi-Cancer Early Detection 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 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.

Congressional Action

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 was introduced in the House by Representatives Jodey Arrington (R-TX), Terri Sewell (D-AL), Richard Hudson (R-NC), Raul Ruiz (D-CA), Mariannette Miller-Meeks (R-IA) and Robin Kelly (D-IL) and in the Senate by Senators Mike Crapo (R-ID), Mike Bennet (D-CO), Tim Scott (R-SC) and Ron Wyden (D-OR). The following is a summary of the legislative language:

	H.R. 842/S. 339
<i>Title</i>	The <i>Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act</i>
<i>What is covered?</i>	MCED test is test for the concurrent detection of multiple cancer types across multiple organ sites furnished on or after January 1, 2028.
	Tests are cleared or approved by FDA.
	Tests are a genomic sequencing blood or blood product test that includes the analysis of cell-free nucleic acids or comparable test determined by the Secretary.
	Secretary must determine the test is reasonable and necessary for the prevention/early detection of an illness or disability and appropriate for individuals entitled to benefits under Part A/enrolled in Part B.
<i>Process</i>	Makes clear the Secretary must use the existing NCD process in making coverage determination. The legislation does not require CMS to cover MCEDs.
<i>Reimbursement amount</i>	For tests furnished before Jan. 1, 2031, the payment amount is equal to the payment for multi-target stool screening DNA test (Cologuard test) in place on date of enactment.
	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.
<i>Age limitations</i>	Beginning Jan 1, 2028, coverage provided for individuals who are 68 years old and under. Each succeeding year, the upper age limit grows by one year. (See below for chart)
<i>Frequency of coverage</i>	Tests cannot be covered more frequently than once per year.

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<i>USPSTF clarification</i>	Clarifies that if the USPSTF recommends MCED tests with an A/B rating CMS can provide coverage under the MIPPA pathway to coverage.
<i>Other cancer screening tests</i>	Clarifies that nothing in this legislation will be construed to affect coverage for existing Medicare cancer screening tests.

A Phased-In Approach

- *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.
- *Payment rate:* The 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.
- *U.S. Preventive Services Task Force (USPSTF):* The language makes clear that if the USPSTF recommends MCED tests with an “A” or “B” rating, then Medicare can choose to cover these tests under the existing pathway that was provided under the Medicare Improvements for Patients and Provider Act, which gives Medicare the authority to cover USPSTF-recommended services if the Secretary determines that such services are appropriate for the Medicare population in which case Medicare would no longer be required to adhere to the phase-in eligibility requirements (see below) or the reimbursement requirements.

- *Phase-in eligibility:* The 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 69 years old and younger.

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
<i>Upper age limit keeps increasing by one year....</i>		

For more information is available at <https://www.fightcancer.org/what-we-do/emergent-science-multi-cancer-early-detection-tests>

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