

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



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) and Terri Sewell (D-AL).

On Thursday, June 27, 2024, the Ways and Means Committee reported a revised version HR 2407 out of committee by a unanimous vote of 38-0. The following chart compares the legislative language of HR 2407 as introduced to the language that was ultimately reported out of the Ways and Means Committee.

	HR 2407 language as <u>introduced</u>	HR 2407 language as reported out of the <u>Ways and Means Committee</u>
<i>Title</i>	The <i>Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act</i>	Same
<i>Findings and Purpose</i>	The legislation includes findings and defines the purpose of the legislation.	No provision
<i>What is covered?</i>	Defines MCED tests as tests furnished to an individual for the purpose of earlier detection of cancer across many cancer types (such as those described in the NCI’s Annual Report to the Nation on the Status of Cancer)	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.	Same
	Tests are a genomic sequencing blood or blood product test that includes the analysis of cell-free	Same

	HR 2407 language as <u>introduced</u>	HR 2407 language as reported out of the <u>Ways and Means Committee</u>
	nucleic acids or comparable test determined by the Secretary	
	No provision	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>	No provision	Makes clear the Secretary must use the existing NCD process in making coverage determination.
<i>Reimbursement amount</i>	No provision	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.
	No provision	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>	No provision	Beginning Jan 1, 2028, coverage provided for individuals who are 67 years old and under. (See below for chart). Each succeeding year, the upper age limit grows by one year.
<i>Frequency of coverage</i>	Coverage provided once a year (once every 11 months)	Same
<i>USPSTF clarification</i>	No provision	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.	Same

ACS CAN Supports These Changes

ACS CAN supports the changes made by the Ways and Means Committee, specifically:

- *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.
- *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.
- *U.S. Preventive Services Task Force (USPSTF):* The revised 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 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.

Age Phase-in Under Ways and Means Language		
Year	Who IS covered	Who is NOT covered
2028	67 years old and younger	68 years old and older
2029	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
<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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