

**Explanation of Changes Reflected in the Chairman’s  
Amendment in the Nature of a Substitute to  
H.R. 2407, *Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening  
Coverage Act***

June 27, 2024

The Chairman’s amendment in the nature of a substitute includes the following changes to H.R. 2407 as introduced:

1. Page 1, Line 3: Strike all after the enacting clause and insert the following:

SECTION 1. Short title.

This Act may be cited as the “Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act”.

SEC. 2. Medicare coverage of multi-cancer early detection screening tests.

(a) Coverage.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(1) in subsection (s)(2)—

(A) by striking the semicolon at the end of subparagraph (JJ) and inserting “; and”; and

(B) by adding at the end the following new subparagraph:

“(KK) multi-cancer early detection screening tests (as defined in subsection (nnn));”; and

(2) by adding at the end the following new subsection:

“(nnn) Multi-CANCER early detection screening tests.—

“(1) IN GENERAL.—The term ‘multi-cancer early detection screening test’ means a test furnished to an individual for the concurrent detection of multiple cancer types across multiple organ sites on or after January 1, 2028, that—

“(A) is cleared under section 510(k), classified under section 513(f)(2), or approved under section 515 of the Federal Food, Drug, and Cosmetic Act;

“(B) is—

“(i) a genomic sequencing blood or blood product test that includes the analysis of cell-free nucleic acids; or

“(ii) a test based on samples of biological material that provide results comparable to those obtained with a test described in clause (i), as determined by the Secretary; and

“(C) the Secretary determines is—

“(i) reasonable and necessary for the prevention or early detection of an illness or disability; and

“(ii) appropriate for individuals entitled to benefits under part A or enrolled under part B.

“(2) NCD PROCESS.—In making determinations under paragraph (1)(C) regarding the coverage of a new test, the Secretary shall use the process for making national coverage determinations (as defined in section 1869(f)(1)(B)) under this title.”.

(b) PAYMENT AND STANDARDS FOR MULTI-CANCER EARLY DETECTION SCREENING TESTS.—

(1) IN GENERAL.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

“(aa) PAYMENT AND STANDARDS FOR MULTI-CANCER EARLY DETECTION SCREENING TESTS.—

“(1) PAYMENT AMOUNT.—The payment amount for a multi-cancer early detection screening test (as defined in section 1861(nnn)) is—

“(A) with respect to such a test furnished before January 1, 2031, equal to the payment amount in effect on the date of the enactment of this subsection for a multi-target stool screening DNA test covered pursuant to section 1861(pp)(1)(D); and

“(B) with respect to such a test furnished on or after January 1, 2031, equal to—

“(i) the amount described in subparagraph (A); or

“(ii) the payment amount determined for such test under section 1834A,

whichever is less.

“(2) LIMITATIONS.—

“(A) IN GENERAL.—No payment may be made under this part for a multi-cancer early detection screening test furnished during a year to an individual if—

“(i) as of January 1 of such year, such individual has attained the age specified in subparagraph (B) for such year; or

“(ii) such a test was furnished to the individual during the previous 11 months.

“(B) AGE SPECIFIED.—For purposes of subparagraph (A)(i), the age specified in this subparagraph is—

“(i) for 2028, 68 years of age; and

“(ii) for a succeeding year, the age specified in this subparagraph for the preceding year, increased by 1 year.

“(3) STANDARDS FOLLOWING USPSTF RATING.—In the case of a multi-cancer early detection screening test that is recommended with a grade of A or B by the United States Preventive Services Task Force, beginning on the date on which coverage for such test is provided pursuant to section 1861(ddd)(1), the preceding provisions of this subsection shall not apply.”.

(2) CONFORMING AMENDMENTS.—

(A) Section 1833 of the Social Security Act (42 U.S.C. 13951) is amended—

(i) in subsection (a)—

(I) in paragraph (1)(D)(i)(I), by striking “section 1834(d)(1)” and inserting “subsection (d)(1) or (aa) of section 1834”; and

(II) in paragraph (2)(D)(i)(I), by striking “section 1834(d)(1)” and inserting “subsection (d)(1) or (aa) of section 1834”; and

(ii) in subsection (h), by striking “section 1834(d)(1)” and inserting “subsections (d)(1) and (aa) of section 1834”.

(B) Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended—

(i) in paragraph (1)—

(I) in subparagraph (O), by striking “and” at the end;

(II) in subparagraph (P), by striking the semicolon at the end and inserting “, and”; and

(III) by adding at the end the following new subparagraph:

“(Q) in the case of multi-cancer early detection screening tests (as defined in section 1861(nnn)), which are not reasonable and necessary for the concurrent detection of multiple cancer types across multiple organ sites;” and

(ii) in paragraph (7), by striking “or (P)” and inserting “(P), or (Q)”.

(c) Rule of construction relating to other cancer screening tests.—Nothing in this section, including the amendments made by this section, shall be construed—

(1) in the case of an individual who undergoes a multi-cancer early detection screening test, to affect coverage under part B of title XVIII of the Social Security Act for other cancer screening tests covered under such title, such as screening tests for breast, cervical, colorectal, lung, or prostate cancer; or

(2) in the case of an individual who undergoes another cancer screening test, to affect coverage under such part for a multi-cancer early detection screening test or the use of such a test as a diagnostic or confirmatory test for a result of the other cancer screening test.