



(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. _____

To amend title XVIII of the Social Security Act to provide for Medicare coverage of multi-cancer early detection screening tests.

IN THE HOUSE OF REPRESENTATIVES

Ms. SEWELL introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title XVIII of the Social Security Act to provide for Medicare coverage of multi-cancer early detection screening tests.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Multi-Cancer
5 Early Detection Screening Coverage Act of 2021”.

6 **SEC. 2. FINDINGS; PURPOSE.**

7 (a) **FINDINGS.**—Congress finds the following:

1 (1) Detecting cancer early, before it has spread
2 throughout the body, saves lives. Cancers detected
3 when still localized can be treated more effectively
4 and have a 5-year cancer specific survival of ap-
5 proximately 90 percent compared with approximately
6 20 percent for cancers found after metastasis has
7 occurred. Existing Medicare-covered early detection
8 tests such as mammograms and colonoscopies, have
9 led to a substantial reduction in age-adjusted mor-
10 tality.

11 (2) Diagnosing and treating cancer earlier often
12 results in less invasive treatments for patients,
13 which are also less expensive. According to peer re-
14 viewed literature, treatment of metastatic cancer is
15 two times more costly than treatment of cancer be-
16 fore it metastasizes.

17 (3) Driving national strategies to broadly detect
18 cancer earlier will help reduce pervasive health dis-
19 parities since racial, ethnic, and geographic groups
20 experience later stages of diagnosis, along with high-
21 er cancer incidence and mortality.

22 (4) The benefits of early cancer detection to
23 Medicare beneficiaries has been limited to five can-
24 cers. According to the National Cancer Institute's
25 Surveillance, Epidemiology, and End Results pro-

1 gram, 71 percent of the 600,000 cancer deaths each
2 year are from types of cancer without a Medicare-
3 covered early detection test.

4 (5) Age is the leading risk factor for cancer,
5 placing Medicare beneficiaries at elevated risk.
6 Americans who are 65 years of age and older are
7 more than 7 times as likely as Americans who are
8 under 65 years of age to be diagnosed with cancer.

9 (6) Several innovative private and academic ef-
10 forts are engaged in research, including advanced
11 clinical trials to develop multi-cancer early detection
12 blood-based tests. Published data indicate that these
13 tests can screen for many cancers at the same time,
14 including rare cancers, with one example currently
15 able to screen for more than 50 cancers.

16 (7) Multi-cancer early detection tests can com-
17 plement the covered early detection tests enacted by
18 Congress and extend the benefits of early detection
19 to more cancers and more Americans. Medicare cov-
20 erage of comprehensive multi-cancer early detection
21 screening tests could substantially transform cancer
22 care for Americans, and the Medicare law needs
23 modernizing to provide timely coverage and keep
24 pace with medical innovation.

1 (b) PURPOSE.—The purpose of this Act is to create
2 a covered benefit for multi-cancer early detection screen-
3 ing tests to ensure Medicare beneficiary access to these
4 tests without unnecessary delay once approved under the
5 Federal Food, Drug, and Cosmetic Act.

6 **SEC. 3. MEDICARE COVERAGE OF MULTI-CANCER EARLY**
7 **DETECTION SCREENING TESTS.**

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

10 (1) in subsection (s)(2)—

11 (A) by striking “and” at the end of sub-
12 paragraph (GG);

13 (B) by striking the period at the end of
14 subparagraph (HH) and inserting “; and”; and

15 (C) by adding at the end the following new
16 subparagraph:

17 “(II) multi-cancer early detection screening
18 tests (as defined in subsection (III));”; and

19 (2) by adding at the end the following new sub-
20 section:

21 “(III) MULTI-CANCER EARLY DETECTION SCREEN-
22 ING TESTS.—The term ‘multi-cancer early detection
23 screening test’ means any of the following tests, approved
24 or cleared by the Food and Drug Administration, fur-
25 nished to an individual for the purpose of early detection

1 of cancer across many cancer types (as categorized in the
2 Annual Report to the Nation on the Status of Cancer
3 issued by the National Cancer Institute):

4 “(1) A genomic sequencing blood or blood prod-
5 uct test that includes the analysis of cell-free nucleic
6 acids.

7 “(2) Such other equivalent tests (which are
8 based on urine or other sample of biological mate-
9 rial) as the Secretary determines appropriate.”.

10 (b) PAYMENT AND FREQUENCY LIMIT.—

11 (1) PAYMENT UNDER FEE SCHEDULE.—Section
12 1833(h) of the Social Security Act (42 U.S.C.
13 1395l(h)) is amended—

14 (A) in paragraph (1)(A), by inserting after
15 “(including” the following: “multi-cancer early
16 detection screening tests under section 1861(l)(l)
17 and including”; and

18 (B) by adding at the end the following new
19 paragraph:

20 “(10) No payment may be made under this
21 part for a multi-cancer early detection screening test
22 (as defined in section 1861(l)(l)) for an individual if
23 such a test was furnished to the individual during
24 the previous 11 months.”.

1 (2) CONFORMING AMENDMENT.—Section
2 1862(a) of the Social Security Act (42 U.S.C.
3 1395y(a)) is amended—

4 (A) in paragraph (1)—

5 (i) in subparagraph (O), by striking
6 “and” at the end;

7 (ii) in subparagraph (P), by striking
8 the semicolon at the end and inserting “,
9 and”; and

10 (iii) by adding at the end the fol-
11 lowing new subparagraph:

12 “(Q) in the case of multi-cancer early de-
13 tection screening tests (as defined in section
14 1861(III)), which are performed more frequently
15 than is covered under section 1833(h)(10);”;
16 and

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

19 (c) RULE OF CONSTRUCTION RELATING TO OTHER
20 CANCER SCREENING TESTS.—Nothing in this section, in-
21 cluding the amendments made by this section, shall be
22 construed—

23 (1) in the case of an individual who undergoes
24 a multi-cancer early detection screening test, to af-
25 fect coverage under part B for other cancer screen-

1 ing tests covered under this title, such as screening
2 tests for breast, cervical, colorectal, lung, or prostate
3 cancer; or

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