

# FAQs on the Multi-Cancer Early Detection Screening Coverage Act



On March 16, 2021, Representatives Terri Sewell (D-AL) and Jodey Arrington (R-TX) re-introduced the *Multi-Cancer Early Detection Screening Coverage Act*, H.R. 1946. On May 27, 2021, Senators Mike Crapo (R-ID) and Michael Bennet (D-CO) introduced the Senate companion, S. 1873. Under the legislation, once multi-cancer screening tests are approved by the FDA, Medicare can then consider whether it wants to cover the tests if clinical benefit is shown. ACS CAN has [endorsed](#) this legislation.

## What are multi-cancer screening tests?

- Multi-cancer screening tests are blood tests that screen for more than one cancer at a time.
- Published data indicate that some of these tests are able to screen for more than 50 cancers – including some rare cancers.
- Several innovative private and academic efforts are engaged in research, including advanced clinical trials, to develop these multi-cancer early detection blood-based tests.

## Are multi-cancer screening tests approved by the FDA today?

- Not yet. The companies engaged in multi-cancer screening have both received breakthrough device designation for their tests and are pursuing FDA approval.

## Why is this legislation needed if the tests aren't yet FDA-approved?

- The legislation will create a pathway at CMS to determine Medicare's coverage of these tests only after the tests have been approved by the FDA.
- Enacting this legislation now – before any multi-cancer early detection test obtains FDA approval – means that once a test receives FDA approval, CMS can begin a process to determine coverage when clinical benefit is shown.

## Will the legislation mandate Medicare to automatically cover multi-cancer screening tests?

- The legislation will not mandate Medicare to cover multi-cancer screening tests.
- The legislation establishes a process for Medicare to determine whether it will cover these new tests and what parameters it will set for coverage.

## If Medicare already covers cancer screening tests, why is this legislation needed?

- Medicare's coverage of preventive services includes currently recommended screenings for specific cancers (such as colorectal prostate, lung, breast, and cervical cancer) that underwent a National Coverage Determination.

## By enacting this legislation, will Medicare no longer cover existing cancer screening tests?

- Nothing in this legislation changes Medicare's coverage of cancer screening tests. Medicare's coverage of existing cancer screening tests remains unchanged.
- This legislation simply creates a pathway for Medicare coverage of multi-cancer screening tests that will be available in addition to – not as a replacement for – existing tests.
- Medicare beneficiaries should continue to receive recommended cancer screenings.

January 20, 2022