

FAQs on the Multi-Cancer Early Detection Screening Coverage Act



On March 16, 2021, Representatives Terri Sewell (D-AL), Jodey Arrington (R-TX), Raul Ruiz (D-CA), and Richard Hudson (R-NC) re-introduced the *Multi-Cancer Early Detection Screening Coverage Act*, HR 1946. This legislation will create a pathway to allow Medicare to cover multi-cancer screening tests once the tests have been approved by the FDA. 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 available in the market 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 available?

- 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.

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.