Life is in the Blood: Medicare Coverage for MCED

By “Coach Vance” Trefethen

***Resolved: The United States federal government substantially reform the use of Artificial Intelligence technology***

Case Summary: Plan passes the Medicare Multi-Cancer Early Detection Screening Coverage Act, a bill pending in Congress but not yet enacted. It amends Title XVIII of the Social Security Act to allow Medicare to cover any MCED tests that are approved by the FDA. MCED is an AI-driven revolutionary technique for early detection of cancer. It can detect cells deposited in the blood that are markers for dozens of types of cancer, many of which have zero methods of early screening today. A simple blood test can catch cancer much earlier and allow treatment before it gets too bad to treat. The “Multi” part is important too: One test catches multiple different possible cancer types, something no test today can do.
 Medicare pays for 1/3 of all cancer treatment in the US every year. But because MCED is so new, and has not received final approval by the FDA (it will happen any day now), Medicare won’t pay for it. It takes specific legislation from Congress to tell Medicare to cover it. The MCED Screening Coverage Act directs Medicare to pay for any MCED approved by the FDA. Our backup evidence specifically advocates passing this bill BEFORE the FDA finalizes the approval, which should stop any whining by Negatives that it’s not ready yet. And some MCED tests have already started rolling out on a limited basis, even without FDA approval - a pretty good indicator that they’re coming soon.
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Life is in the Blood: Medicare Approval for MCED

In Leviticus 17:11, the Bible says “the life of the flesh is in the blood.” In the centuries since, doctors have discovered just how true that is. A revolutionary new use of Artificial Intelligence in blood tests can provide early diagnosis of cancer and save lives, if you join us in affirming that: The United States Federal Government should substantially reform the use of artificial intelligence technology.

OBSERVATION 1. DEFINITIONS

Substantial

Merriam Webster Online Dictionary copyright 2021. <https://www.merriam-webster.com/dictionary/substantially> (accessed 28 May 2021)

**:**considerable in quantity **:**significantly great

Reform

Merriam Webster Online Dictionary copyright 2021 <https://www.merriam-webster.com/dictionary/reform> (accessed 28 May 2021)

**:**to put or change into an improved form or condition

MCED – Multi-Cancer Early Detection technology. It uses Artificial Intelligence to diagnose cancer in blood samples

Stephen Ezell 2021 (vice president, global innovation policy, at the Information Technology and Innovation Foundation) 19 Apr 2021 “Seizing the Transformative Opportunity of Multi-cancer Early Detection” <https://itif.org/publications/2021/04/19/seizing-transformative-opportunity-multi-cancer-early-detection> (accessed 7 Nov 2021)

Multi-cancer early detection approaches merge emerging biological and information technologies—including next-generation gene sequencing, artificial intelligence, and big data—in a revolutionary new approach to cancer detection.

**END QUOTE. HE GOES ON TO SAY LATER QUOTE:**

MCED screening represents a groundbreaking technology now in the advanced stages of development that is poised to contribute to a step change in cancer screening and care. MCED represents perhaps the most sophisticated application of the emerging technique of liquid biopsy: the detection of cancers using biomarkers circulating in human fluids (e.g., blood), such as circulating tumor cells and circulating cell-free tumor DNA (ctDNA).

OBSERVATION 2. INHERENCY, the structure of the Status Quo. Two key FACTS:

FACT 1. Undetectable Cancer.

Most cancers are undetectable with current early screening techniques

British Journal of Cancer 2021 ([Allan Hackshaw](https://www.nature.com/articles/s41416-021-01498-4#auth-Allan-Hackshaw) (with Cancer Research UK & University College London Cancer Trials Centre, London).  [Sarah S. Cohen](https://www.nature.com/articles/s41416-021-01498-4#auth-Sarah_S_-Cohen) and Heidi Reichert (with EpidStrategies, A Division of ToxStrategies, Inc., USA).   [Anuraag R. Kansal](https://www.nature.com/articles/s41416-021-01498-4#auth-Anuraag_R_-Kansal), [Karen C. Chung](https://www.nature.com/articles/s41416-021-01498-4#auth-Karen_C_-Chung) and [Joshua J. Ofman](https://www.nature.com/articles/s41416-021-01498-4#auth-Joshua_J_-Ofman) (are with GRAIL, an MCED development company). British Journal of Cancer is a  twice-monthly professional [medical journal](https://en.wikipedia.org/wiki/Medical_journal) publishing papers by clinicians and scientists. ) 21 Aug 2021 “Estimating the population health impact of a multi-cancer early detection genomic blood test to complement existing screening in the US and UK” https://www.nature.com/articles/s41416-021-01498-4

There are currently only four recommended population-level screening programmes: breast, lung, colorectal, and cervical cancers, because of a favourable benefit-harm balance. Together, these four cancers represent only 29% of total cancer incidence and 24% of cancer-related deaths in the US among individuals aged 50–79 (Supplemental Fig. [1](https://www.nature.com/articles/s41416-021-01498-4#MOESM1)). Also, adherence is below national targets in the US and England. In the US, prostate screening is only recommended on an individualised basis. There is, as yet, no effective screening test for all other cancer types, and many are unlikely to ever be associated with cost-effective single-cancer screening programmes because they each have relatively low incidence and mortality.

FACT 2. Multi Cancer Detection needed.

We need Multi-Cancer Early Detection, but it’s not covered by Medicare – and more than 300 advocates say it should be

The Prevent Cancer Foundation 2021. (United States-based non-profit organization; one of the leading US health organizations devoted to the early detection and prevention of cancer) “Multi Cancer Early Detection – Coverage and Legislation” <https://www.preventcancer.org/multi-cancer-early-detection/coverage-and-legislation/#coverage-act> (accessed 7 Nov 2021)

Currently, MCED tests are not covered by insurance. The Prevent Cancer Foundation and more than 300 advocacy organizations and cancer centers support the Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021. This legislation would authorize the Centers for Medicare & Medicaid Services (CMS) to evaluate and cover blood-based multi-cancer early detection tests and future test methods (e.g., urine or hair tests), once approved by the Food and Drug Administration (FDA). Under current law, Medicare coverage of preventive services is limited to tests for which Congress has explicitly authorized coverage.  Private insurers cover screening tests that receive an “A” or “B” recommendation from the U.S. Preventive Services Task Force (USPSTF).  In the absence of congressional action, it could take several years after FDA approval before Medicare beneficiaries can receive coverage for MCED tests. This bill would greatly reduce such access delays for seniors while allowing CMS to use its evidence-based process to determine coverage.

OBSERVATION 3. We offer the following PLAN implemented by Congress and the President

1. Congress passes the Medicare Multi-Cancer Early Detection Screening Coverage Act. This bill amends Title XVIII of the Social Security Act to allow Medicare to cover any MCED tests that are approved by the FDA.

2. Funding through increased IRS enforcement of existing tax laws.
3. Enforcement through existing agencies that already enforce Medicare reimbursement rules.
4. Timeline: Plan takes effect one day after an affirmative ballot.
5. All Affirmative speeches may clarify

OBSERVATION 4. SOLVENCY. We see this in 2 sub-points

A. Coverage is Crucial. The MCED Coverage Act is crucial to making MCED widely available

Business Wire 2020. (news service) 4 Sept 2020 “National Minority Quality Forum Urges Action on Multi-Cancer Early Detection (MCED)” <https://www.businesswire.com/news/home/20201204005552/en/National-Minority-Quality-Forum-Urges-Action-on-Multi-Cancer-Early-Detection-MCED> (brackets added) (accessed 8 Nov 2021)

"Patient risk is increased, precious lives are lost, and avoidable costs are incurred when potentially life-saving care is inaccessible," said [Gary] Puckrein [PhD; president of National Minority Quality Forum]. "Leaders in Congress understand this and have taken this crucial step to introduce The Multi-Cancer Early Detection Screening Coverage Act, which modernizes Medicare so that seniors will have the opportunity to benefit from these important technological advances in the battle against cancer."

B. One-tenth the cost. MCED costs less than 1/10 as much as current methods, and more than doubles the number of cancers detected.

**Even if the entire U.S. population were using MCED (which our Plan doesn’t do, we’re only doing Medicare patients), the annual cost would be $3 billion for testing and follow-up diagnostics combined**

British Journal of Cancer 2021 ([Allan Hackshaw](https://www.nature.com/articles/s41416-021-01498-4#auth-Allan-Hackshaw) (with Cancer Research UK & University College London Cancer Trials Centre, London).  [Sarah S. Cohen](https://www.nature.com/articles/s41416-021-01498-4#auth-Sarah_S_-Cohen) and Heidi Reichert (with EpidStrategies, A Division of ToxStrategies, Inc., USA).   [Anuraag R. Kansal](https://www.nature.com/articles/s41416-021-01498-4#auth-Anuraag_R_-Kansal), [Karen C. Chung](https://www.nature.com/articles/s41416-021-01498-4#auth-Karen_C_-Chung) and [Joshua J. Ofman](https://www.nature.com/articles/s41416-021-01498-4#auth-Joshua_J_-Ofman) (are with GRAIL, an MCED development company). British Journal of Cancer is a  twice-monthly professional [medical journal](https://en.wikipedia.org/wiki/Medical_journal) publishing papers by clinicians and scientists. ) 21 Aug 2021 “Estimating the population health impact of a multi-cancer early detection genomic blood test to complement existing screening in the US and UK” <https://www.nature.com/articles/s41416-021-01498-4> (“less than 1/10 comes from $7060 for MCED divided by $89,042 for current methods. The reason the total cost for MCED isn’t 1/10 of $16.9 billion currently is that more people would get tested with MCED compared to current testing. Each test is cheaper but more tests would be done.)

The total estimated diagnostic investigation cost associated with current screening was $16.9 billion ($0.4 billion for true positives plus $16.5 billion for false positives), and $3.09 billion for the incremental MCED test assuming the extreme of 100% uptake (Fig. [1](https://www.nature.com/articles/s41416-021-01498-4#Fig1)), and that in both cases all screen positives undergo further investigations. Although this represents an extra cost, more than double the number of cancers could be detected (422,105 vs. 189,498). The diagnostic cost per cancer detected using the four single-cancer tests is $89,042, but only $7060 with the incremental MCED test.

ADVANTAGE 1. Lives saved

MCED would bring huge savings of life by detecting cancer in time to treat it

Federal Trade Commission 2021. Docket No. 9401 Complaint - In the matter of Illumina Inc. and Grail Inc. 30 March 2021 (accessed 7 Nov 2021) https://www.ftc.gov/system/files/documents/cases/redacted\_administrative\_part\_3\_complaint\_redacted.pdf

MCED tests are poised to revolutionize how cancer is detected and treated, having the potential to save millions of lives in the United States and around the world. **[END QUOTE**]Although cancer is the second leading cause of death in the United States, healthcare providers currently are able to screen for only a small number of cancer types, testing for one cancer at a time. Doctors currently lack the option to broadly screen for multiple types of cancer using a single test. As a result, the vast majority of cancers are only detected after patients exhibit symptoms, when it is often too late to treat the cancer effectively. [**LATER IN THE CONTEXT HE CONCLUDES QUOTE:**] Rather than wait for cancer symptoms to arise, MCED tests use a “liquid biopsy” process to examine fragments of DNA in the bloodstream to determine whether cancer cells have shed any DNA. The vast majority of tumors shed cancer cells, making detection of cancer through liquid biopsy possible at very early stages of the disease and allowing for early treatment that could dramatically improve patients’ outcomes.

ADVANTAGE 2. Economic benefits

Even a 1% reduction in cancer mortality would be significant: $500 billion in total economic benefit

Prof. Kevin M. Murphy and Prof. Robert Topel 2009. ( Murphy - Professor of Economics at the University of Chicago's Booth School of Business. Topel - Professor in Urban and Labor Economics at the University of Chicago's Booth School of Business) <https://www.resources.org/common-resources/the-value-of-health-and-longevity-kevin-m-murphy-and-robert-h-topel/> (accessed 8 Nov 2021)

Even though the United States now spends more than $50 billion a year in medical research, about 40 percent of which is federally funded, substantially greater expenditures might be worthwhile given that the returns to basic medical research may be quite large. For example, using our estimate that a 1 percent reduction in cancer mortality would be worth about $500 billion, spending an additional $100 billion on cancer research and treatment would be worthwhile if it has a one-in-five chance of reducing mortality by 1 percent.

ADVANTAGE 3. Taxpayer savings.

A. The Link: Medicare pays about 1/3 of the annual $177 billion cost of treating cancer. That’s $59 billion

Stephen Ezell 2021 (vice president, global innovation policy, at the Information Technology and Innovation Foundation) 19 Apr 2021 “Seizing the Transformative Opportunity of Multi-cancer Early Detection” <https://itif.org/publications/2021/04/19/seizing-transformative-opportunity-multi-cancer-early-detection> (accessed 7 Nov 2021)

Thus, despite some progress, cancer still afflicts millions annually and imposes tremendous costs on the U.S. health care system, as well as the broader economy. Cancer is the second-most-costly disease in the United States.  Cancer accounts for an estimated 5 to 11 percent of the annual total U.S. health care budget.  In 2017, cancer care cost the United States an estimated $177 billion (an increase of approximately 39 percent since 2010), equivalent to 1 percent of U.S. gross domestic product (GDP).  Medicare—the federally administered health care program that covers more than 60 million seniors and persons with disabilities—shoulders roughly one-third of this cost annually.

B. The Impact: Early detection of cancer would save 17% of the annual cost of treatment

Stephen Ezell 2021 (vice president, global innovation policy, at the Information Technology and Innovation Foundation) 19 Apr 2021 “Seizing the Transformative Opportunity of Multi-cancer Early Detection” <https://itif.org/publications/2021/04/19/seizing-transformative-opportunity-multi-cancer-early-detection> (accessed 7 Nov 2021)

Similarly, a 2017 study, “Estimating Cost Savings for Early Cancer Diagnosis,” sought to examine the cost savings from early cancer diagnosis for 19 cancers, assuming that all stage III and IV cases were detected at stage I or II instead (using current incidence rates for these cancers). As the report notes, “In many cases, it is much less costly to treat cancer when it is diagnosed earlier.” In part, that’s because cancer patients’ costs of care in the last year of life are sizably higher than during early stages. The study concluded that earlier diagnosis of those cancers could generate $26 billion in cost savings annually, equivalent to 17 percent of total estimated yearly expenditures on cancer treatment.

2A Evidence: MCED

DEFINITIONS & BACKGROUND

Text of the bill

Text of HR8845 2020. (official web site of Congress) 3 Dec 2020 “H.R. 8845 To amend title XVIII of the Social Security Act to provide for Medicare coverage of multi-cancer early detection screening tests” <https://www.congress.gov/bill/116th-congress/house-bill/8845/text?r=1&s=1> (accessed 8 Nov 2021)



[CONTINUED ON NEXT PAGE]



Summary of what the MCED Coverage Act does

US Senate Finance Committee 2021. “Crapo, Bennet Introduce Bipartisan Bill to Ensure Medicare Beneficiaries Receive Coverage for Cancer Detection Technologies” 27 May 2021 <https://www.finance.senate.gov/ranking-members-news/crapo-bennet-introduce-bipartisan-bill-to-ensure-medicare-beneficiaries-receive-coverage-for-cancer-detection-technologies> (accessed 8 Nov 2021)

Congress has previously acted before to ensure Medicare coverage for other cancer screenings, including mammography and colorectal screenings.  The Medicare Multi-Cancer Early Detection Screening Coverage Act would:

Create authority for the Centers for Medicare and Medicaid Services (CMS) to cover the latest diagnostic technologies, once approved by the Food and Drug Administration (FDA), including blood-based multi-cancer early detection tests and future test methods that draw on samples of urine or hair;

Maintain CMS authority to use an evidence-based process to determine coverage parameters for these new tests;

State that new diagnostic technologies will supplement, not replace, existing screenings and will not impact existing coverage and cost-sharing; and

Direct the Government Accountability Office to issue a report that tracks utilization and makes recommendations to expand usage.

TOPICALITY

MCED = a use of AI

Stephen Ezell 2021 (vice president, global innovation policy, at the Information Technology and Innovation Foundation) 19 Apr 2021 “Seizing the Transformative Opportunity of Multi-cancer Early Detection” <https://itif.org/publications/2021/04/19/seizing-transformative-opportunity-multi-cancer-early-detection> (accessed 7 Nov 2021)

In summary, AI-enabled machine learning has become an increasingly prevalent tool in the biomedical community. With a high degree of accuracy, it’s enabling the identification of the presence of cancers from ctDNA circulating in the bloodstream and the ability to connect that identification to the tissue of origin, just as it’s facilitating the identification of cancerous cells based on an examination of images or facilitating the identification of cellular or metabolic processes as a basis for new drug development. As such, the increasing application of AI-based systems to disease detection and drug discovery represents a genuine revolution in the approach to modern medicine in general, and to cancer detection in particular.
The Benefits of Multi-cancer Early Detection Screening
Blood-based, MCED technologies are poised to bring a multitude of benefits to individual patients, health care systems, and even entire economies more broadly.

Details on how AI is used for cancer detection

Stephen Ezell 2021 (vice president, global innovation policy, at the Information Technology and Innovation Foundation) 19 Apr 2021 “Seizing the Transformative Opportunity of Multi-cancer Early Detection” <https://itif.org/publications/2021/04/19/seizing-transformative-opportunity-multi-cancer-early-detection> (accessed 7 Nov 2021) (In this context “GRAIL” is a company that is developing MCEDs)

As part of its clinical development program, GRAIL assembled “the largest linked datasets of genomic and clinical data in the cancer field” and applied machine learning analytics to determine which of three different next-generation sequencing approaches—mutations, chromosomal alterations, or methylation patterns—would provide the optimal method of detecting cancer. (GRAIL’s clinical trial has enrolled over 145,000 participants.) The company trained its machine learning algorithms to distinguish patterns of cancer from non-cancer while filtering out technical and biological noise, enabling it to distinguish genetically heterogeneous cancer cfNA from other cfNA that are indicative of non-cancerous conditions.

INHERENCY

A/T “Use existing screening methods” – Most cancer in the US happen with types that have no screening option today

Stephen Ezell 2021 (vice president, global innovation policy, at the Information Technology and Innovation Foundation) 19 Apr 2021 “Seizing the Transformative Opportunity of Multi-cancer Early Detection” <https://itif.org/publications/2021/04/19/seizing-transformative-opportunity-multi-cancer-early-detection> (accessed 7 Nov 2021)

The five types of cancer with guideline-recommended screening options represent approximately 40 percent of the total cancer incidence in the United States, yet only 15 to 20 percent of cancer diagnoses when test performance and compliance are accounted for, according to an analysis of 2006 to 2015 data from the National Institutes of Health’s (NIH) Surveillance, Epidemiology, and End Results (SEER) Program. Overall, about 70 percent of all U.S. cancer deaths occur in cancers with no recommended screening options.

SOLVENCY / ADVOCACY / ADVANTAGES

Examples of Advocacy

MCED Coverage is needed to get the benefits of MCED to our citizens

Stephen Ezell 2021 (vice president, global innovation policy, at the Information Technology and Innovation Foundation) 19 Apr 2021 “Seizing the Transformative Opportunity of Multi-cancer Early Detection” <https://itif.org/publications/2021/04/19/seizing-transformative-opportunity-multi-cancer-early-detection> (accessed 7 Nov 2021)

MCED holds the potential, over time, to transform America’s cancer-detection paradigm from one in which most cancers are detected when patients present symptomatically to one in which they can be screen-detected in advance. ▪ If U.S. enterprises are to lead in this fast-emerging, intensely globally competitive technology field—and if citizens are to enjoy the benefits—then policymakers will need to get the regulatory and coverage environment right. ▪ Congress should pass the Medicare Multi-Cancer Early Detection Screening Coverage Act, which authorizes the Centers for Medicare & Medicaid Services to use an evidence-based process to cover blood-based MCED tests.

Specific advocacy/solvency: MCED Coverage Act will save lives

Julio Fuentes 2021 (*President and CEO of the Florida State Hispanic Chamber of Commerce*) 2 Nov 2021 “Better news on the horizon for Hispanics at risk for cancer” <https://www.theledger.com/story/opinion/2021/11/02/better-news-horizon-hispanics-risk-cancer/8569131002/> (accessed 9 Nov 2021)

Right now, under current law, Medicare cannot quickly cover FDA-approved preventive screenings and something like these multi-cancer tests could be inaccessible for many years before doctors and patients can access them. The bipartisan Medicare Multi Cancer Early Detection Screening Coverage Act, co-sponsored by Rep. Soto, creates a pathway for Medicare coverage of these technologies and, if signed into law, will enable more cancers to be found at an earlier, more treatable stage, saving lives.

National Minority Quality Forum supports MCED Coverage Act because it will save lives

Business Wire 2020. (news service) 4 Sept 2020 “National Minority Quality Forum Urges Action on Multi-Cancer Early Detection (MCED)” <https://www.businesswire.com/news/home/20201204005552/en/National-Minority-Quality-Forum-Urges-Action-on-Multi-Cancer-Early-Detection-MCED> (brackets added) (accessed 8 Nov 2021)

The National Minority Quality Forum (NMQF) today announced its support for [The Multi-Cancer Early Detection Screening Coverage Act (H.R. 8845)](https://cts.businesswire.com/ct/CT?id=smartlink&url=https%3A%2F%2Fsewell.house.gov%2Fsites%2Fsewell.house.gov%2Ffiles%2Fdocuments%2FBill%2520Text.pdf&esheet=52343258&newsitemid=20201204005552&lan=en-US&anchor=The+Multi-Cancer+Early+Detection+Screening+Coverage+Act+%28H.R.+8845%29&index=1&md5=ba41c96f23b3cd72cbb869fb7de57de1), sponsored by U.S. Reps. Terri Sewell (AL-07), Jodey Arrington (TX-19), Raul Ruiz (CA-36), and Richard Hudson (NC-08). Cancer is the second leading cause of death in the United States, robbing more than 620,000 Americans of their lives every year. H.R. 8845 paves the way for Medicare coverage of emerging multi-cancer early detection tests (MCED), innovative technology that has the potential to have a positive impact on cancer morbidity and mortality rates for all populations, including, but not limited to, reducing inequities in cancer treatment and outcomes for communities of color.

A/T “FDA hasn’t approved MCEDs yet”

FDA approval is anticipated shortly

Reuters news service 2021. “FTC Challenges Vertical Merger Involving Cancer Screening Tests” 6 Apr 2021 <https://uk.practicallaw.thomsonreuters.com/Document/Ic6d00b0a961e11ebbea4f0dc9fb69570/View/FullText.html?transitionType=Default&contextData=(sc.Default)&firstPage=true> (accessed 11 Nov 2021)

Grail is one of a number of firms racing to develop multi-cancer detection (MCED) tests. Grail's test, Galleri, is poised for an initial limited launch for use in specific circumstances in 2021, and Food and Drug Administration (FDA) approval is anticipated shortly thereafter.

Won’t be long: The “Galleri” test is being rolled out right now in California, Washington and Oregon

Jamie Reno 2021. (award-winning investigative reporter) 1 November 2021 This New Test Can Detect 50 Types of Cancer from a Single Blood Draw, HEALTHLINE <https://www.healthline.com/health-news/this-new-test-can-detect-50-types-of-cancer-from-a-single-blood-draw> (the last sentence ends as shown here, with no period, in the original article) (accessed 9 Nov 2021)

In March, GRAIL [announced](https://grail.com/press-releases/grail-announces-first-health-system-to-offer-galleri-novel-multi-cancer-early-detection-blood-test/) that Providence, a leading regional health system based in Renton, Washington, will be the first U.S. health system to offer Galleri as a complement to single cancer screening tests. The Galleri test initially will be used by Providence at its California, Washington, and Oregon points of care. It could eventually be available across Providence’s entire seven-state footprint. That includes more than 50 hospitals and nearly 1,100 health clinics serving 5 million patients. [Dr. Amy Compton-Phillips](https://www.linkedin.com/in/amycomptonphillips/), chief clinical officer at Providence, said the company will integrate the Galleri test into clinical care. “When combined with the power of our genomics research, having a single blood test that can detect more than 50 cancers advances our goal of finding cancer early, enabling our providers to administer treatment when it’s most likely to be successful and giving our patients the opportunity to achieve the best possible outcomes,” she said in a [press statement](https://grail.com/press-releases/grail-announces-first-health-system-to-offer-galleri-novel-multi-cancer-early-detection-blood-test/). [Hans Bishop](https://www.bloomberg.com/profile/person/16571841), the former CEO of GRAIL, said in the statement in March 2021 that GRAIL’s partnership with Providence “moves us that much closer to making a tremendous and potentially life-altering difference for patients and providers.” In addition, the test will be [available](https://www.cbsnews.com/news/cancer-blood-test-early-detection/) by the end of this year in Mayo Clinic facilities in Rochester, Minnesota as well as Jacksonville, Florida, and Phoenix, Arizona. People can request the test from their doctor. Health insurance, however, doesn’t yet cover it. People [need to pay](https://www.cbsnews.com/news/cancer-blood-test-early-detection/) $949 out of pocket to cover it

Better to pass MCED Coverage Act before they’re approved, to avoid several years of delayed availability

The Prevent Cancer Foundation 2021. (United States-based non-profit organization; one of the leading US health organizations devoted to the early detection and prevention of cancer) “Multi Cancer Early Detection – Coverage and Legislation” <https://www.preventcancer.org/multi-cancer-early-detection/coverage-and-legislation/#coverage-act> (accessed 7 Nov 2021)

**What are the benefits of introducing legislation before FDA approval of MCED tests?** Passing legislation can be a lengthy process. By starting now, it is possible to have legislation enacted by the time these new tests are approved by the FDA and prevent significant patient access delays. If Congress decides not to introduce legislation until tests are approved by the FDA, patients could face several years of access delays as the legislative process moved forward.

A/T “Funding”

Increased enforcement of existing tax laws would increase federal revenues by $1 trillion over the next decade

Galen Hendricks & Seth Hanlon 2021 (*Hendricks is a research associate at the Center for American Progress. Hanlon is a senior fellow at the Center* ) 19 Apr 2021 “Better Tax Enforcement Can Advance Fairness and Raise More Than $1 Trillion of Revenue” <https://www.americanprogress.org/issues/economy/reports/2021/04/19/498311/better-tax-enforcement-can-advance-fairness-raise-1-trillion-revenue/> (accessed 17 June 2021)

The good news is that Congress and the Biden administration have an opportunity this year to begin rebuilding the IRS’ enforcement capabilities, direct new resources toward thoroughly auditing high-income taxpayers and corporations, and modernize the agency’s computer systems in a way that will improve both compliance and taxpayer service. By taking these steps, the United States can increase revenues by more than $1 trillion over a decade, according to multiple estimates.  In other words, investments in tax enforcement would pay for themselves and could pay for other critical investments at the same time.

A/T “More study needed”

Studies already underway worldwide on AI-driven cancer detection

Stephen Ezell 2021 (vice president, global innovation policy, at the Information Technology and Innovation Foundation) 19 Apr 2021 “Seizing the Transformative Opportunity of Multi-cancer Early Detection” <https://itif.org/publications/2021/04/19/seizing-transformative-opportunity-multi-cancer-early-detection> (accessed 7 Nov 2021)

Elsewhere, a *Nature* article notes that researchers throughout the world are similarly starting to develop these types of Artificial Intelligence (AI)-driven, methylation-based cancer classification systems. As *Nature*explains:
 Full-genome methylation analysis checks for small hydrocarbon molecules attached to DNA. The addition of such methyl groups is one of the mechanisms behind epigenetics—when the activity of genes is altered without any mutation to the underlying genetic code—and different types of cancer show different patterns of methylation.

AIt’s already been studied and it’s already working. Example: Germany

Stephen Ezell 2021 (vice president, global innovation policy, at the Information Technology and Innovation Foundation) 19 Apr 2021 “Seizing the Transformative Opportunity of Multi-cancer Early Detection” <https://itif.org/publications/2021/04/19/seizing-transformative-opportunity-multi-cancer-early-detection> (accessed 7 Nov 2021)

Researchers throughout the world are applying such methylation approaches to cancer detection. For instance, researchers at the German Cancer Research Center in Heidelberg, Germany, have developed an AI-driven, methylation-based classifier originally trained to sort medulloblastomas into subtypes, which they have now expanded to cover all of the approximately 100 known cancers of the central nervous system. The methylation-based classified developed by the team in Germany now recognizes about 150 different cancer entities, and is helping to make more-accurate cancer diagnoses—their algorithm found that 12 percent of the brain tumors studied had actually been misdiagnosed by pathologists.

Economic Benefits

Even a 1% reduction in cancer mortality would deliver $500 billion in total economic benefit

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The tremendous costs cancer imposes conversely suggest tremendous benefits if cancers could be detected earlier when treatments are more likely to succeed and as more-effective treatments and therapeutics for cancer are invented. In fact, Murphy and Topel, considering the benefits of increased longevity and improved quality of life, find that a 1 percent reduction in mortality from cancer could deliver roughly $500 billion in net present benefits, while a cure (if one could be achieved) could deliver $50 trillion in present and future benefits.

Lives Saved

Quantification: Early detection = 4 times higher survival rate (89% versus 21%)

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Overall, patients’ survival rates are 5 to 10 times greater when cancer is detected at an early stage rather than at a late stage. When cancer is diagnosed after it has spread, the five-year cancer-specific survival rate is 21 percent, compared with 89 percent when the cancer is diagnosed early and still localized.

Taxpayer Savings

Earlier diagnosis would cut cost of treatment for 19 types of cancer by $26 billion/year (divide by 3 for savings to Medicare)

…because Medicare pays for 1/3 of the cancer treatment in the US (ADV-3-A card)

Stephen Ezell 2021 (vice president, global innovation policy, at the Information Technology and Innovation Foundation) 19 Apr 2021 “Seizing the Transformative Opportunity of Multi-cancer Early Detection” <https://itif.org/publications/2021/04/19/seizing-transformative-opportunity-multi-cancer-early-detection> (accessed 7 Nov 2021)

Similarly, a 2017 study, “Estimating Cost Savings for Early Cancer Diagnosis,” sought to examine the cost savings from early cancer diagnosis for 19 cancers, assuming that all stage III and IV cases were detected at stage I or II instead (using current incidence rates for these cancers). As the report notes, “In many cases, it is much less costly to treat cancer when it is diagnosed earlier.” In part, that’s because cancer patients’ costs of care in the last year of life are sizably higher than during early stages. The study concluded that earlier diagnosis of those cancers could generate $26 billion in cost savings annually, equivalent to 17 percent of total estimated yearly expenditures on cancer treatment.

Top 5 types of cancer (in addition to 19 above) would save $10.7 billion/year with early detection (divide by 3 for Medicare savings)

…because Medicare pays for 1/3 of the cancer treatment in the US (ADV-3-A card)

Stephen Ezell 2021 (vice president, global innovation policy, at the Information Technology and Innovation Foundation) 19 Apr 2021 “Seizing the Transformative Opportunity of Multi-cancer Early Detection” <https://itif.org/publications/2021/04/19/seizing-transformative-opportunity-multi-cancer-early-detection> (accessed 7 Nov 2021)

For breast, lung, prostate, and colorectal cancers, and melanoma, which are the top-five cancers in the United States by incidence, with an estimated 859,110 new cases in 2017 (accounting for 50.9 percent of the 1,688,780 cancer cases diagnosed that year), the study estimated $10.7 billion in savings from earlier diagnosis (about 41.5 percent of cost savings from all cancers).

DISAD RESPONSES

A/T “False positives” – MCED is far better than current tests on the rate of false positives

**Current tests get 43 false positive results for every 1 person that actually does have cancer. MCED gets 1.8 false positive results for every 1 person that actually does have cancer.**

British Journal of Cancer 2021 ([Allan Hackshaw](https://www.nature.com/articles/s41416-021-01498-4#auth-Allan-Hackshaw) (with Cancer Research UK & University College London Cancer Trials Centre, London).  [Sarah S. Cohen](https://www.nature.com/articles/s41416-021-01498-4#auth-Sarah_S_-Cohen) and Heidi Reichert (with EpidStrategies, A Division of ToxStrategies, Inc., USA).   [Anuraag R. Kansal](https://www.nature.com/articles/s41416-021-01498-4#auth-Anuraag_R_-Kansal), [Karen C. Chung](https://www.nature.com/articles/s41416-021-01498-4#auth-Karen_C_-Chung) and [Joshua J. Ofman](https://www.nature.com/articles/s41416-021-01498-4#auth-Joshua_J_-Ofman) (are with GRAIL, an MCED development company). British Journal of Cancer is a  twice-monthly professional [medical journal](https://en.wikipedia.org/wiki/Medical_journal) publishing papers by clinicians and scientists. ) 21 Aug 2021 “Estimating the population health impact of a multi-cancer early detection genomic blood test to complement existing screening in the US and UK” <https://www.nature.com/articles/s41416-021-01498-4> (accessed 8 Nov 2021)(brackets added)

In the US, an estimated 189,498 breast, lung, colorectal and cervical cancers are found through current recommended screening, with 8,057,657 false positives (Figs. [1](https://www.nature.com/articles/s41416-021-01498-4#Fig1) and [2a](https://www.nature.com/articles/s41416-021-01498-4#Fig2), Table [1](https://www.nature.com/articles/s41416-021-01498-4#Tab1)). The TP:FP [true positive to false positive] ratio is therefore 1:43 **[END QUOTE**] (to detect one person with any of these four cancers, 43 people without these cancers may have diagnostic investigations following a screen-positive result). The estimate of 189,498 represents 15% of all cancers (CDR). [**THEY GO ON TO WRITE QUOTE**:] Using an MCED blood test in addition to current recommendations could detect an extra 422,105 cancers (Fig. [2a](https://www.nature.com/articles/s41416-021-01498-4#Fig2), Table [1](https://www.nature.com/articles/s41416-021-01498-4#Tab1)), including 95,262 breast, cervical, colorectal and lung cancers, and 326,843 other cancers, such as head and neck, liver, bladder, stomach, ovary, oesophagus and lymphoma and lung cancer in low-risk individuals (Fig. [2a](https://www.nature.com/articles/s41416-021-01498-4#Fig2)). This is associated with an additional 1,162,433 test positives of which 740,329 are false positives. Although this represents many additional individuals who may be referred for cancer investigations, the screening efficiency is very high (TP:FP, 1:1.8): to detect one person with cancer only 1.8 people without cancer may undergo diagnostic investigations, among those with a positive MCED test.

A/T “False positives” – Some MCED have 0.7% false positive rate

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In March 2020, in an Annals of Oncology article, “Sensitive and specific multi-cancer detection and localization using methylation signatures in cell-free DNA,” GRAIL published clinical test data from its Circulating Cell-free Genome Atlas (CCGA) study.  The study found that an earlier version of the company’s cancer detection technology, Galleri, could, through a single blood draw, detect cancer signals from more than 50 cancer types across all stages, with a very low false positive rate of 0.7 percent, and moreover that when a cancer signal is detected, it can be linked to the cancer signal of origin (i.e., where in the body the cancer is coming from) with 93 percent accuracy.

A/T “Deters people from using existing screening” – Study found continued use of standard screening even with MCED

British Journal of Cancer 2021 ([Allan Hackshaw](https://www.nature.com/articles/s41416-021-01498-4#auth-Allan-Hackshaw) (with Cancer Research UK & University College London Cancer Trials Centre, London).  [Sarah S. Cohen](https://www.nature.com/articles/s41416-021-01498-4#auth-Sarah_S_-Cohen) and Heidi Reichert (with EpidStrategies, A Division of ToxStrategies, Inc., USA).   [Anuraag R. Kansal](https://www.nature.com/articles/s41416-021-01498-4#auth-Anuraag_R_-Kansal), [Karen C. Chung](https://www.nature.com/articles/s41416-021-01498-4#auth-Karen_C_-Chung) and [Joshua J. Ofman](https://www.nature.com/articles/s41416-021-01498-4#auth-Joshua_J_-Ofman) (are with GRAIL, an MCED development company). British Journal of Cancer is a  twice-monthly professional [medical journal](https://en.wikipedia.org/wiki/Medical_journal) publishing papers by clinicians and scientists. ) 21 Aug 2021 “Estimating the population health impact of a multi-cancer early detection genomic blood test to complement existing screening in the US and UK” <https://www.nature.com/articles/s41416-021-01498-4> (accessed 8 Nov 2021)

One important consideration is whether having an MCED test deters people from participating in current screening programmes whose tests may have higher sensitivities. However, in the CancerSEEK study MCED results were reported and acted upon, but participants continued to have high adherence to standard screening.

A/T “High follow-up diagnostic localization costs” – MCED correctly locates the cancer 93% of the time, so localization costs are minimal

**Localization diagnostic costs happen when a test tells you “you have cancer” but doesn’t tell you where in your body it is (or tells you incorrectly). But MCED produces results that are correct as to the source of the cancer 93% of the time, so there won’t be a lot of useless follow-up tests looking for the source of the problem.**

British Journal of Cancer 2021 ([Allan Hackshaw](https://www.nature.com/articles/s41416-021-01498-4#auth-Allan-Hackshaw) (with Cancer Research UK & University College London Cancer Trials Centre, London).  [Sarah S. Cohen](https://www.nature.com/articles/s41416-021-01498-4#auth-Sarah_S_-Cohen) and Heidi Reichert (with EpidStrategies, A Division of ToxStrategies, Inc., USA).   [Anuraag R. Kansal](https://www.nature.com/articles/s41416-021-01498-4#auth-Anuraag_R_-Kansal), [Karen C. Chung](https://www.nature.com/articles/s41416-021-01498-4#auth-Karen_C_-Chung) and [Joshua J. Ofman](https://www.nature.com/articles/s41416-021-01498-4#auth-Joshua_J_-Ofman) (are with GRAIL, an MCED development company). British Journal of Cancer is a  twice-monthly professional [medical journal](https://en.wikipedia.org/wiki/Medical_journal) publishing papers by clinicians and scientists. ) 21 Aug 2021 “Estimating the population health impact of a multi-cancer early detection genomic blood test to complement existing screening in the US and UK” <https://www.nature.com/articles/s41416-021-01498-4> (accessed 8 Nov 2021)

Finally, MCED tests need to be able to identify the location of the primary tumour to guide further workup, and we did not allow for the cost of incorrect localisation. For the MCED test we considered, the localisation appears to be correct 93% of the time when a cancer signal is detected , and thus increases in diagnostic workup costs following incorrect localisation would be a small increment to the overall costs.

A/T “Medicare is bad” - Medicare’s costs are increasing consistent with or lower than private health insurance

John Rother 2012 (president and chief executive of the National Coalition on Health Care, a nonprofit organization that gets funding from health providers and purchasers, and from consumer groups ) 24 Feb 2012 Five myths about Medicare <https://www.washingtonpost.com/opinions/five-myths-about-medicare/2012/02/02/gIQAnXxtXR_story.html> (accessed 9 Nov 2021)

The trustees of Medicare last year [projected](https://www.cms.gov/ReportsTrustFunds/downloads/tr2011.pdf) that the program’s share of gross domestic product would increase from the current 3.7 percent to about 5 percent in 2030 and nearly 6 percent by 2050. But since Medicare’s inception in 1965, its spending growth, on a per-person basis, has stayed consistent with or lower than the increase in private health insurance premiums.

A/T “Medicare is bad” - Whatever cost problems Medicare has, the rest of the health care system has them too

John Rother 2012 (president and chief executive of the National Coalition on Health Care, a nonprofit organization that gets funding from health providers and purchasers, and from consumer groups ) 24 Feb 2012 Five myths about Medicare <https://www.washingtonpost.com/opinions/five-myths-about-medicare/2012/02/02/gIQAnXxtXR_story.html> (accessed 9 Nov 2021)

When politicians call for restructuring the program to save money, missing from the discussion has been the clear need for additional revenue over the longer term to support the inflow of 30 million more people between now and 2030. Even the most well-run and efficient program cannot nearly double its enrollment without a matching increase in money. Containing health-care cost growth is critical for Medicare’s survival, but it’s impossible to do that for Medicare alone. Payment restraints and incentives that improve value must be applied to the entire health-care system to be effective.

A/T “Medicare drives up medical costs” – Technology drives up medical costs. New equipment is expensive, and then people live longer and consume more medical care during the extra years

Brett Matsumoto and Caleb Cho 2020 (economists, Office of Prices and Living Conditions, U.S. Bureau of Labor Statistics) “What is driving increases in healthcare spending? Observations from BLS disease-based price indexes,” *Beyond the Numbers: Prices & Spending*, vol. 9, no. 17 U.S. Bureau of Labor Statistics, December 2020 <https://www.bls.gov/opub/btn/volume-9/what-is-driving-increases-in-healthcare-spending.htm> (accessed 9 Nov 2021)

The United States has experienced significant increases in nominal healthcare spending between 2005 and 2015. Key driving factors behind the rapid spending growth vary across diseases. However, technology plays a pivotal role in rising healthcare spending on the most common diseases. On one hand, medical technology can directly increase treatment cost per case by introducing more expensive equipment and medications into the market. Technological improvements can also increase the number of people who receive treatments for diseases over time and thus total expenditures as well. On the other hand, high-tech drugs and devices improve survival rates and lifespans for patients.