



March 31, 2025

**Stephanie Carlton**  
**Acting Administrator**  
**Centers for Medicare and Medicaid Services**  
**7500 Security Blvd.**  
**Baltimore, MD 21244**

Dear Acting Administrator Carlton,

As organizations that share a strong commitment to Medicare beneficiaries, taxpayers, and healthcare consumers, we would like to express our concerns regarding the final coverage determination for “Genetic Testing in Oncology: Specific Tests” issued by Novitas Solutions and First Coast Service Options.<sup>1</sup> Published in January, the final determination removed coverage from nine previously covered genetic diagnostic cancer tests. Barring any additional action by April, patients and their care teams will lose access to essential testing for diagnosing and managing treatment. We urge you to step in and ensure this Local Coverage Determination (LCD) does not enter into effect.

We have serious concerns regarding the Medicare Administrative Contractors’ (MACs) LCD process. In December 2016, Congress enacted the 21<sup>st</sup> Century Cures Act which aims to accelerate the development of medical products and improve access for patients to new treatments and cures.<sup>2</sup> The Act includes amendments to increase transparency around the LCD process and how decisions are reached which include “a response to comments submitted to the contractor with respect to such proposed determination” and “[a]n explanation of the rationale that supports such determination.”<sup>3</sup>

However, in the eight years since the law’s implementation, MAC practices have diverged from the system established by the legislation, leaving patients endlessly uncertain about the future of their care and limiting the development of innovative medical care. All patients, most of all those with cancer, can benefit greatly from timely access to diagnostic tools to ensure they are receiving the treatment plan that best meets their needs.

Issues with how MACs reach their coverage determination decisions can be seen throughout the history of the “Genetic Testing in Oncology: Specific Tests” LCD. In 2023, Novitas hurriedly reissued the LCD on

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<sup>1</sup> L39365 available at <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=39365&ver=131>

<sup>2</sup> Food and Drug Administration, “21st Century Cures Act [agency resources],” Jan. 31 2020, <https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act>.

<sup>3</sup> Public Law 114–255, 2016, <https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf>.

July 27, after withdrawing their original final LCD, which was set to go into effect on July 17, due to procedural errors out of step with 21<sup>st</sup> Century Cures and the Medicare Program Integrity Manual.<sup>4,5</sup> Unusually, the LCD relied on outside, non-governmental compendia to determine which diagnostic tests should be covered by Medicare, disregarding the responsibility of the MACs to review evidence and make coverage determinations with clear rationale as outlined by policy.

Moreover, in July 2024, CMS had the opportunity to let the LCD retire at its one-year mark, after Novitas and First Coast Service Options failed to issue a decision. However, CMS granted the MACs an extension to continue deliberations over the medical necessity and reasonableness of the tests, all without considering newly published research or additional documentation. This has resulted in the LCD finalized in January relying on significantly out-of-date publications.

Unfortunately, the problem with MACs is not unique to the “Genetic Testing in Oncology: Specific Tests” LCD. The Biden Administration allowed the LCD process to deviate seriously from the letter of law, producing decisions that were rife with flaws and countless errors.

In April 2024, it came to light that MACs had ignored the recommendations of expert physicians and limited access to blood tests for organ transplant patients to monitor if their bodies were rejecting their new organ.<sup>6</sup> These experts had almost unanimously advised that the blood testing “had significant clinical benefits, including for routine testing.” Despite this, MACs moved to dramatically cut Medicare coverage for such tests.

If our nation wishes to be a leader in medical innovation, we must ensure those who most need it are able to access the latest advances in care. While government-provided insurance tends to lead to worse outcomes than privately provided care, any government system CMS must, at a minimum, make transparent, consistent, and evidence-based coverage determinations that keep costs low for taxpayers. Without coverage of these tests, clinicians and patients will not use them, and will lose access to individualized information that is critical for patient care. In absence of these tests, physicians will instead turn to more invasive, and costly, options to manage patients. This is a burden not only for patients but also for taxpayers. This strains the Medicare system and reinforces a one-size-fits-all approach to healthcare, often leading to the over-treatment of patients.<sup>7</sup> For the same reason, many vulnerable patients will not get the life-saving care they need.

Early diagnosis and personalized treatment of cancer makes a dramatic difference in patient outcomes and survival rates.<sup>8</sup> One-size-fits-all care sentences many seniors to unnecessary burden and suffering. This makes access to genetic testing for cancer critical and determinations that do not consider the scientific evidence – like the ones made by Novitas and First Coast Service Options – unjustifiable.

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<sup>4</sup> DL39365 available at [https://localcoverage.cms.gov/mcd\\_archive/view/lcd.aspx?lcdInfo=39364:24](https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=39364:24)

<sup>5</sup> L39365 available at <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=39365&ver=131>

<sup>6</sup> Daniels, Cheyanne M. 2024. “Medicare Ignored Expert Advice to Cut Tests for Transplant Patients: Report.” The Hill. April 19, 2024. <https://thehill.com/policy/healthcare/4606446-medicare-ignored-expert-advice-to-cut-tests-for-transplant-patients/>.

<sup>7</sup> National Cancer Institute, “Financial Burden of Cancer Care | Cancer Trends Progress Report,” Mar. 2024, [https://progressreport.cancer.gov/after/economic\\_burden](https://progressreport.cancer.gov/after/economic_burden).

<sup>8</sup> Crosby D, Bhatia S, Brindle KM, Coussens LM, Dive C, Emberton M, Esener S, Fitzgerald RC, Gambhir SS, Kuhn P, Rebbeck TR, Balasubramanian S, “Early detection of cancer,” *Science*, Mar. 2022,

Now, more than ever, America's healthcare system is in dire need of reform. Unjustifiable coverage determination are just another step toward unaccountable bureaucracy.

Our organizations are focused on ensuring the best outcomes for patients, healthcare providers, and taxpayers. **We strongly urge CMS to work in the best interests of America's cancer patients and rescind the Genetic Testing in Oncology LCD due to the actions of wayward MACs. We ask that the new administration conduct a fresh review of the relevant scientific data and analysis and issue its own determinations.**

Thank you for your consideration of our comments.

Sincerely,

**Saul Anuzis**

President

60 Plus | American Association of Senior Citizens

**Steve Pociask**

Chief Executive Officer and Founder

American Consumer Institute

**Andy Mangione**

Senior Vice President

Association of Mature American Citizens Action

**Jeffrey L. Mazzella**

President

Center for Individual Freedom

**George Landrith**

President

Frontiers of Freedom Institute

**Mario H. Lopez**

President

Hispanic Leadership Fund

**David Williams**

President

Taxpayers Protection Alliance