



AdvaMed

Advanced Medical Technology Association

1301 Pennsylvania Avenue, NW

Suite 400

Washington, D.C. 20004

P :: 202.783.8700

F :: 202.783.8750

W :: AdvaMed.org

A. Scott Whitaker

President and CEO

Direct :: 202 434 7200

swhitaker@advamed.org

February 29, 2024

Administrator Chiquita Brooks-LaSure
Centers for Medicaid & Medicare Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

When President Obama signed the overwhelmingly bipartisan 21st Century Cures Act into law in 2016, the FDA received the authority to expedite the review of “breakthrough” medical devices to diagnose or treat life-threatening or irreversibly debilitating conditions. The message was clear: Cut through the red tape to ensure access to safe, effective breakthrough medical technologies for every patient in need.

CMS has done too little to ensure the 21st Century Cures Act delivers for Medicare beneficiaries. We are left with no other conclusion than that the agency is simply unwilling to implement this bipartisan policy, based on the lack of progress on breakthrough medtech since the beginning of this Administration.

First, in late 2021 CMS repealed the Medicare Coverage of Innovative Technology (MCIT) policy – which itself had bipartisan congressional support – finalized by the previous Administration. At the time, the agency assured American seniors that it would propose a revised version of MCIT.

In 2022, again in April 2023, and again later that spring, CMS promised to release this revision.

Finally, and only after significant pressure from multiple stakeholders across the health care spectrum, including patient groups and Congress itself, CMS released a Transitional Coverage for Emerging Technologies notice on June 22, 2023. AdvaMed welcomed this action and submitted technical recommendations for improving the proposal on August 28, 2023.

In November 2023, CMS yet again promised a finalized TCET notice.



Months later, Medicare beneficiaries suffering from conditions for which they and their doctors have exhausted all possibilities are still waiting for CMS to act on their behalf. Countless technical experts outside the agency stand ready to help. AdvaMed has provided recommendations and insights at every step in the process.

Meanwhile, experts repeatedly sound the alarm on the cost of delay to patients:

Dr. Josh Makower of Stanford University told a House subcommittee last May: “Simply put, America’s seniors and patients across the country are all too often not getting timely access to critical medical technologies for many years, if ever.” His studies indicate that years lapse between FDA’s clearance of medical technologies and Medicare patients’ access to those technologies. A continuous glucose monitor or technology to prevent a stroke during certain medical procedures could spare patients devastating medical catastrophes. Diabetic shock or a stroke could cost patients their health, mobility, and even their lives, yet all of that could be prevented through access to the right medical technology, he testified.

Dr. Lishan Aklog, a cardiac surgeon, medtech innovator, and CEO of two small innovative medtech companies, explained to another House subcommittee last July that most innovation comes from small companies like his, which has commercialized technology to prevent esophageal cancer through early precancer detection. This cancer kills 16,000 Americans each year, two-thirds in the Medicare population. Many of those deaths are likely preventable with these innovative technologies. Without predictable coverage, patients die, and innovation driven by small companies withers on the vine.

As Dr. Aklog pointed out, his small company’s work to detect esophageal cancer early aligns with the 21st Century Cures Act and would have a major impact on President Biden’s Cancer Moonshot. Cutting cancer deaths by half in 25 years requires Medicare coverage of such innovative medical devices, including revolutionary diagnostic technologies excluded from CMS’s proposed TCET notice.

CMS’s delay in finalizing TCET is puzzling. The ability to establish a workable policy to ensure Medicare coverage of safe, effective, FDA-designated and market-authorized breakthrough devices should be easily within the agency’s grasp.

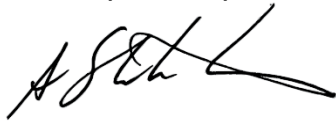
Medicare beneficiaries have waited long enough—too long—for coverage of breakthrough medical technologies to prevent, diagnose, and treat the chronic conditions from which they are suffering unnecessarily. Eighty-one medical technologies both authorized and designated as “breakthrough” by FDA have been effectively denied by CMS to Medicare beneficiaries for years through CMS inaction. Beneficiaries are right to ask: Why, if FDA has declared a medical technology safe, effective, and the kind of breakthrough they might need, Medicare denies them access to these breakthrough technologies for years?



On behalf of the entire medical technology industry, I urge you to release a final notice as soon as possible. We remain available to provide guidance on all technical and policy matters that will help CMS accomplish this milestone, as we have been since this bipartisan policy was repealed nearly three years ago. We also continue to work with congressional allies who understand the value of this policy. Whether through CMS regulation or congressional action, it is time to get the job done.

The subcommittee hearing where Dr. Aklog testified was titled: "Innovation Saves Lives" CMS is obligated to act on what he rightly called that simple truth.

Thank you for your consideration,



Scott Whitaker

