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OPINION: Medicare must keep pace with FDA-authorized breakthrough medical technologies

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Every day, doctors across America diagnose Medicare beneficiaries with life-threatening or debilitating conditions, then face a frustrating reality: much of the most promising medical technology available to help those patients is already authorized by the Food and Drug Administration for patient use, yet still unavailable because Medicare coverage has not caught up.

The gap between FDA authorization and Medicare coverage is not an abstract policy problem. It is a real, persistent barrier that delays access to medtech-enabled care for those who could benefit from it the most. Too often, Medicare beneficiaries are forced to wait years for coverage of technologies the FDA has already reviewed and determined to be safe and effective for patients with serious unmet medical needs.

Congress recognized the importance of speeding patient access to transformative technologies when it created the FDA's Breakthrough Devices Program in the 21st Century Cures Act. The program was designed to accelerate the review of medtech that provides more effective treatment or diagnosis for conditions than currently exist, while maintaining FDA's rigorous standards for safety and effectiveness.

But while FDA has delivered on its end of that bargain, Medicare coverage has not kept pace.

Growing evidence shows that for technologies requiring a new Medicare coverage pathway, nearly six years can pass between FDA market authorization and Medicare coverage.

That means older Americans may wait the better part of a decade for access to innovations specifically designed to help patients like them. For those facing serious illness, that delay can mean fewer options, worse outcomes and missed opportunities for earlier intervention.

Some critics misunderstand the FDA's breakthrough program, suggesting it represents a shortcut to market or a weakening of evidentiary standards. That is not true. Breakthrough designation is not an approval, nor is it a waiver of FDA requirements. All breakthrough-designated devices must meet the same standards as any other medical technology — whether through the 510(k), de novo or premarket approval pathways. In fact, only a small fraction of breakthrough-designated devices ultimately receive FDA market authorization, underscoring the rigor of the process.

FDA evaluates compelling evidence — including clinical data, real-world evidence, and preclinical studies — to determine whether a device meets those criteria. Once authorized, these technologies are subject to ongoing post-market surveillance to ensure continued safety and effectiveness. Far from lowering the bar, FDA applies the global gold standard of scientific review.

Despite this rigorous process, Medicare patients still face long delays before they can benefit from these FDA-authorized innovations. These delays are especially challenging for small manufacturers and startups that drive much of America's medtech innovation and lack the resources to navigate years of uncertainty in coverage decisions.

At the end of President Donald Trump's first term, Medicare instituted the Medicare Coverage of Innovative Technologies (MCIT) policy, a tremendous step forward for Medicare patients in need of FDA-cleared breakthrough treatments. Unfortunately, the Biden administration repealed MCIT, leaving Medicare beneficiaries without access to these remarkable breakthrough medical technologies. Then, after repeal, they took three years to analyze the MCIT program. Finally, after years of delay, the Biden administration replaced MCIT with a watered-down Transitional Coverage for Emerging Technologies (TCET) pathway. While better than no policy at all, it is not adequate to ensure seniors see the promise of these amazing new technologies.

We are encouraged by the willingness of current CMS leadership, including Centers for Medicare and Medicaid Services Administrator Mehmet Oz, to revisit accelerated coverage pathways more akin to MCIT.

Lawmakers on both sides of the aisle have made encouraging progress with their introduction of the Ensuring Patient Access to Critical Breakthrough Products Act (H.R. 5343/S. 1717). This legislation would provide temporary Medicare coverage for FDA-cleared breakthrough technologies while CMS conducts a structured evaluation for permanent coverage. It preserves rigorous oversight, supports evidence development and ensures patients and physicians can access breakthrough innovations whenever needed.

AdvaMed, the leading trade association for medtech innovators, along with patient advocacy organizations and dozens of state medtech associations, are calling for passage of this legislation for a more predictable, timely Medicare coverage pathway for breakthrough medical technologies that have already been rigorously cleared by FDA.

No one is asking for preferential treatment. AdvaMed, Medicare beneficiaries, and bipartisan leaders in the House and Senate are simply asking for Medicare to recognize FDA's scientific determination and to avoid duplicative, yearslong reviews that stand between patients and care.

The question is no longer whether Medicare should cover treatments involving these breakthrough technologies. The question is how quickly we can ensure that the coverage becomes a reality.

Patients shouldn't have to wait years to benefit from innovations the FDA has already determined to be safe and effective. Congress has an opportunity to fix this longstanding gap, strengthen America's leadership in medical technology and ensure Medicare policy keeps pace with modern medicine. We urge lawmakers to act because timely access can make all the difference for patients.

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