



Breakthrough Medtech Innovation Is Here. Now Congress Must Help Patients Access It.



Scott Whitaker | Opinion
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At the annual Medtech Showcase and Reception on Capitol Hill, members of Congress experienced more than 30 cutting-edge medical technologies firsthand, gaining a glimpse into the future of patient care. And yet too many breakthrough medical technologies remain out of reach for patients, awaiting Medicare coverage even after receiving FDA authorization for patients. If FDA has determined a technology is safe and effective, why should Medicare beneficiaries have to wait — more often than not, years — to access it? Congress has an opportunity to fix this, once and for all.

The Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway recently released by the Centers for Medicare & Medicaid Services demonstrates that the Administration recognizes the problem. This marks a significant step in the right direction by helping create a more predictable Medicare coverage process for certain FDA-authorized medical technologies. But administrative pathways like RAPID and its predecessors are not a permanent fix, since future administrations can undo this progress.

Congress can provide certainty through the Ensuring Patient Access to Critical Breakthrough Products Act, which would establish a permanent, predictable coverage pathway. At this year's Medtech Showcase and Reception, members of Congress saw just how valuable breakthrough technologies are.

The exhibits included an at-home brain-stimulation device for patients with moderate to severe major depressive disorder; a wearable fall-detection device designed to help identify falls that can lead to serious injuries, including hip fractures; and a catheter-based heart valve for patients who are not good candidates for open-heart surgery.

These are technologies designed for serious unmet medical needs, yet Medicare coverage can depend on whether a product fits neatly into an existing benefit category, whether billing codes are available, or whether a hospital can absorb costs while coverage and payment decisions catch up. For older Americans facing aggressive cancers, advanced heart disease, neurodegenerative conditions, or diabetes, delays in Medicare coverage of FDA-authorized medtech are more than bureaucratic hurdles.

A prominent study found a median delay of 5.7 years from FDA authorization to Medicare coverage. The delays can mean years without access to state-of-the-art diagnostic tools, minimally invasive implants, or novel surgical systems. Some patients may pay substantial out-of-pocket costs or settle for a less advanced or targeted treatment without access to the helpful medtech just out of their reach.

Medtech startups also face obstacles to their success, and post-authorization coverage delays can create extra financial strain as companies navigate the so-called "valley of death" between FDA authorization and reliable Medicare coverage and payment. When coverage takes years, investment slows, making it harder for U.S. companies to develop new technologies, create manufacturing jobs, and bring the next generation of medtech to market at home.

Bridging this divide and reducing wait times for Medicare coverage will have a meaningful impact on America's health care system and supercharge our already-robust medtech innovation ecosystem. This starts with establishing a more durable Medicare coverage pathway for breakthrough medtech that earns FDA authorization. These reforms would enable companies to continue developing the innovative technologies we're proud of in this country, protecting the three million jobs that medtech supports across the U.S., and bringing patients the tools for a better, stronger, and faster recovery.

Congress does not need to imagine the future of medicine. Members saw it on display at this year's showcase. The question is whether Medicare beneficiaries will be allowed to benefit from it. Now is the time for Congress to end the uncertainty and pass the Ensuring Patient Access to Critical Breakthrough Products Act.

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