

# Congress of the United States

Washington, DC 20515

April 21, 2026

Secretary Robert F. Kennedy Jr.  
Department of Health and Human Services  
200 Independence Ave. SW  
Washington, DC 20201

Administrator Mehmet Oz  
Centers for Medicare & Medicaid Services  
7500 Security Blvd.  
Baltimore, MD 21244

Dear Secretary Kennedy and Administrator Oz,

We write to express strong support for comprehensive Medicare coverage of breakthrough medical device technologies. These revolutionary medical technologies offer hope for patients who have few, if any, options.

As you know, the 21<sup>st</sup> Century Cures Act<sup>1</sup> established a new pathway for “breakthrough” medical devices to receive accelerated review by the Food and Drug Administration (FDA). The Breakthrough Devices Program is available to certain medical devices that provide a more effective treatment option or diagnosis capability than what is already available. These devices must meet the FDA’s “rigorous standards for device safety and effectiveness in order to be authorized for marketing.”<sup>2</sup> This program is essential to giving patients access to innovative technologies, while still ensuring they are safe and effective. Several groundbreaking technologies have benefited from this program, including,

- Blood tests to support earlier Alzheimer's disease diagnosis;<sup>3</sup>
- Non-invasive cancer therapy that uses low-intensity electric fields to disrupt cancer cell division and slow tumor growth;<sup>4</sup> and
- Next generation bone grafts for treating spine deterioration.<sup>5</sup>

While the Breakthrough Devices Program establishes a designated FDA pathway for review of novel devices, after FDA approval, there is often a multi-year lag for Medicare coverage due to Medicare’s Coverage Determination Process. On average, 44% of novel technologies authorized by the FDA between 2016 and 2019 achieved nominal Medicare coverage by the end of 2022.<sup>6</sup> The median time to achieve this nominal coverage was over five years.<sup>7</sup> These delays can negatively impact seniors’ access to innovative technologies and harm overall health outcomes.

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<sup>1</sup> Public Law 114-255

<sup>2</sup> [Breakthrough Devices Program | FDA](#)

<sup>3</sup> [FDA 510\(k\) Premarket Notification](#)

<sup>4</sup> [FDA Approves First-of-Its-Kind Device to Treat Pancreatic Cancer](#)

<sup>5</sup> [FDA Premarket Approval](#)

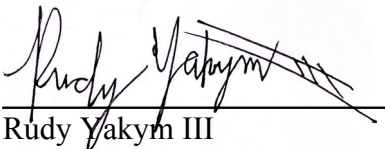
<sup>6</sup> JAMA Health Forum - Time from Authorization by the US Food and Drug Administration to Medicare Coverage for Novel Technologies (August 2023)

Congress has been working to provide a dedicated coverage pathway for these technologies by advancing the *Ensuring Patient Access to Critical Breakthrough Products Act (H.R.5343)*. This bill creates a 4-year temporary Medicare coverage pathway for breakthrough devices upon FDA approval. The manufacturer and CMS would then work together during the transitional coverage period on a permanent coverage decision. This bill received strong bipartisan support from the Ways and Means Committee during its markup in September 2025. It passed out of Committee 37-3.


Both the Trump Administration and the Biden Administration have acknowledged the importance of providing Medicare coverage for these devices. While Congress works through the legislative process, we request that CMS use H.R. 5343 as a model for new regulation to ensure access to these innovative treatment and diagnostic devices. The *Ensuring Patient Access to Critical Breakthrough Products Act* includes important patient guardrails that we would like to see included in any final rule including, the requirement that manufacturers provide sufficient clinical data that includes the Medicare population, the coverage for breakthrough devices is only for the breakthrough indication of the device, and that the Secretary of Health and Human Services has the ability to deny coverage through this pathway if they determine the device presents risk of harm. We also urge CMS to ensure that any new or enhanced pathway includes provisions that address potential fraud, waste, and abuse issues. In some cases, these devices are seniors' only option, and we need to ensure they have affordable access to these novel technologies.

Thank you for your attention to this important issue. We look forward to partnering with you to advance this policy. Please do not hesitate to reach out if you have any questions.

Sincerely,



Rudy Yakym III  
Member of Congress



Blake D. Moore  
Member of Congress

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<sup>7</sup> JAMA Health Forum - Time from Authorization by the US Food and Drug Administration to Medicare Coverage for Novel Technologies (August 2023)



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Terri A. Sewell  
Member of Congress



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Gus M. Bilirakis  
Member of Congress



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Lori Trahan  
Member of Congress



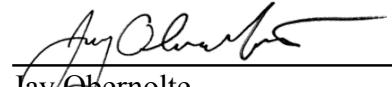
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Suzan K. DelBene  
Member of Congress



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Earl L. "Buddy" Carter  
Member of Congress



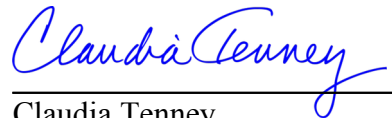
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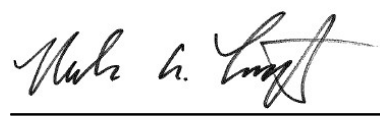
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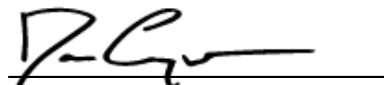
Randy K. Weber, Sr.  
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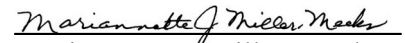
Randy Feenstra  
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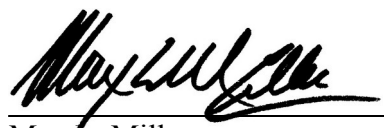
Dan Meuser  
Member of Congress



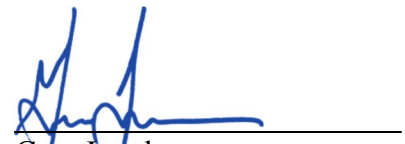
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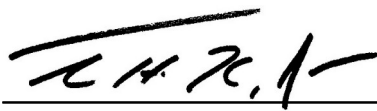
Kevin Mullin  
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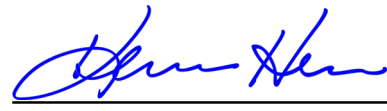
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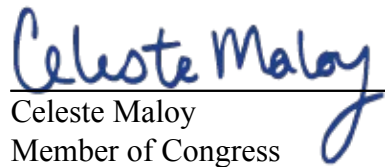
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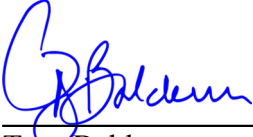
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Ron Estes  
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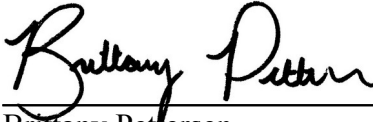
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Troy Balderson  
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David Kustoff  
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Sarah McBride  
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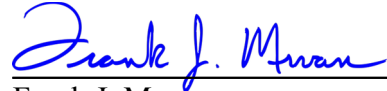
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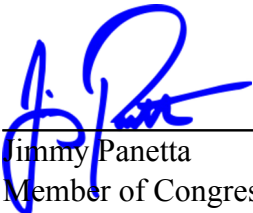
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Jake Auchincloss  
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Ami Bera, M.D.  
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