

Congress of the United States
Washington, DC 20515

November 23, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

We write to express our disappointment in your decision to repeal the Medicare Coverage for Innovative Technology (MCIT) rule which would have provided access to innovative and life-saving medical devices for Medicare beneficiaries. Going forward, we urge you to expeditiously propose policies in its place to achieve the bipartisan goals of the MCIT rule by providing our nation's seniors and people with disabilities access to breakthrough devices and encouraging future life-saving medical innovation.

As you know, as part of the bipartisan 21st Century Cures Act signed into law by President Obama, Congress codified the Food & Drug Administration (FDA) Breakthrough Devices Program and created the "breakthrough" approval pathway. This voluntary pathway allows ground-breaking medical devices and diagnostics to receive priority review if they address unmet medical needs or offer more effective treatment or diagnosis of life-threatening or debilitating diseases.

Unlike drugs, which are generally covered by CMS once approved by the FDA, many seniors today can't access FDA-approved medical devices and diagnostics unless they participate in various clinical studies. These studies may take years – adding more data collection and process milestones to an already lengthy FDA-approval process. Additionally, medical innovators, many of them small businesses, must navigate a patchwork of Local Coverage Determinations (LCDs) or claim-by-claim adjudication by Medicare Administrative Contractors (MACs) if they do not have a National Coverage Determination (NCD) which may take additional months or years to secure. This expensive, time-consuming, and confusing set of processes for Medicare coverage of innovative health technology needs to be improved.

The MCIT rule streamlines the Medicare coverage pathway for breakthrough products by allowing for temporary national coverage for breakthrough FDA devices or diagnostics for up to four years. During this temporary coverage period, FDA's post-market surveillance requirements would remain intact to ensure these products are safe and effective. The rule also provides for termination of MCIT coverage if the FDA revokes market authorization for a device or issues either a warning letter or medical device safety communication against the product.

As part of the FDA breakthrough approval process, breakthrough products must be found to be a "more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions" and satisfy one of the following criteria:

- Represent a breakthrough technology;
- No approved or cleared alternatives exist;
- Offer significant advantages over existing approved or cleared alternatives; or

- Device availability is in the best interest of patients.¹

These unique devices can be distinguished from other medical device because by definition they address unmet needs of patients with severe, debilitating illness who do not have other options. The MCIT rule provides a clear pathway to coverage and allows providers to use their informed, clinical judgment to treat Medicare patients based on existing medical protocols and the latest science while considering unique patient needs.

A permanent withdrawal of the MCIT rule may delay future innovative medical devices and diagnostic tools. If the rule were to be implemented, instead of spending months or years navigating the health care bureaucracy to receive coverage after FDA approval, medical innovators could prioritize their time and resources to collect data to demonstrate their product's impact on patients and educate providers how to best serve their patients with these innovative products. The MCIT rule could further encourage early investors to step in to address our most critical health care challenges and successfully deliver life-changing treatments to patients.

The multiple postponements and repeal of the MCIT rule may have delayed patient access to breakthrough devices over the last several months. To fully capture stakeholder feedback, we recommend that effective date changes in future rulemaking be subject to public notice and comment while maintaining access to these breakthrough products. We encourage any future rule-making to accommodate patients who may have benefitted from this coverage had it gone into effect as originally finalized.

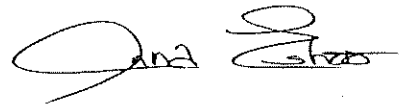
We do not support repealing the existing MCIT rule. However, as you consider separate rulemaking in its place to address implementation issues raised in your November 12th rule, we urge you to retain the crucial components of the MCIT rule by providing for immediate or near-immediate temporary coverage of breakthrough devices - both for prospectively and retrospectively approved devices - for a similarly reasonable period of time.

Thank you for your careful consideration of our request. We appreciate your continued interest in medical innovation, and we look forward to continuing to work with you on these issues.

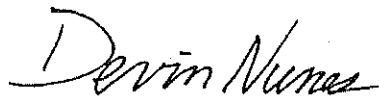
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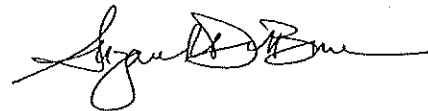
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¹ FDA Breakthrough Devices Program, [Breakthrough Devices Program](#) | FDA

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