

United States Senate
WASHINGTON, DC 20510

November 5, 2021

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

Dear Administrator Brooks-LaSure:

We are writing to express our support for the timely creation of a new Medicare Coverage for Innovative Technologies (MCIT) rule. The Centers for Medicare and Medicaid Services (CMS) should continue its ongoing efforts to develop flexible coverage pathways and improve access to innovative devices, and we urge CMS to move quickly in issuing a new proposed rule.

Innovative medical technologies improve the quality of life for Americans experiencing disabilities, injuries, or chronic conditions. A new MCIT rule could help ensure that Medicare patients have access to medical devices or device-led combination products with a Breakthrough Device designation after they are cleared by the Food and Drug Administration.

We understand that CMS proposed repealing the existing rule after experts raised concerns about operationalization and patient benefit during the comment process. CMS should address these concerns and move forward with a pathway for coverage that allows for collection of appropriate evidence for Breakthrough Devices. We urge CMS to develop a new rule that addresses coverage for innovative and demonstrably beneficial technologies that balances access with patient protections. Focused improvements to the MCIT pathway will allow for coverage that is flexible, predictable, and evidence-based.

Through robust and clear rulemaking, CMS has the opportunity to continue its essential work guaranteeing access to innovative treatments and technologies for Medicare beneficiaries. We encourage you to move quickly to help improve the lives of the patients who stand to gain from these technologies.

Sincerely,



Margaret Wood Hassan
United States Senator



Todd Young
United States Senator



Michael F. Bennet
United States Senator



John Barrasso
United States Senator



Jeanne Shaheen
United States Senator



Bill Cassidy, M.D.
United States Senator



Mark Kelly
United States Senator



Ben Sasse
United States Senator



Kyrsten Sinema
United States Senator



Marsha Blackburn
United States Senator