FOCUSED ULTRASOUND FOUNDATION

1230 Cedars Court, Suite 206
Charlottesville, VA 22903

434.220.4993 TEL
434.220.4978 FAX
www.fusfoundation.org

October 15, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Re: CMS-3372-P2— Medicare Program: Medicare Coverage of Innovative Technology and Definition of Reasonable and Necessary

Dear Administrator Brooks-LaSure:

We appreciate the opportunity to offer the following comments on the proposed rule repealing the "Medicare Coverage of Innovative Technology (MCIT)" program. We are disappointed with the proposed repeal and believe it will limit Medicare beneficiaries' equitable access to important breakthrough treatments. Ensuring FDA-approved medical technologies that improve care and avoid wasted expenditures is vital to ensuring meaningful access to innovations that are deemed reasonable and necessary.

We offer views from the perspective of a 501(c)(3) medical technology research, education and advocacy organization dedicated to advancing the development and clinical adoption of focused ultrasound, a noninvasive therapeutic medical device technology, for the treatment of a wide range of medical conditions. The Focused Ultrasound Foundation was founded in 2006 to accelerate the development and adoption of focused ultrasound to improve the lives of countless individuals with serious medical disorders. Patients are always central to our mission and we aim to bring focused ultrasound treatments to patients as quickly as possible because we have seen the great impact these treatments can have on the lives of so many.

One of the most critical factors limiting widespread and equitable patient access to focused ultrasound therapies, and other highly innovative medical device technologies, is the lag time between FDA clearance and coverage and reimbursement. For Medicare beneficiaries, it is often surprising that a therapy would be deemed safe and effective by the FDA yet not available for them due to lack of CMS coverage. Without coverage and reimbursement,

clinicians may be unable to offer innovative treatments like focused ultrasound to their patients, despite clinical evidence demonstrating that the treatment could be less invasive, with less risk of complications, and could offer an improved quality of life as compared to other standard treatments.

The MCIT program as proposed in the previously finalized rule would grant automatic Medicare coverage to devices deemed "breakthrough" by the FDA, immediately upon their FDA marketing authorization. This coverage would extend for four years, during which time the manufacturer would be able to collect additional evidence required for a long-term coverage policy.

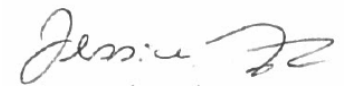
The MCIT program would eliminate the gap between FDA clearance and Medicare coverage for innovative medical devices, providing more certainty to manufacturers, more tools in clinicians' armamentarium to treat disease, and more universal and equitable treatment options for patients. The FDA provides the global gold standard for medical technology regulation and can be a valuable partner to CMS in ensuring safe and effective innovations are available to patients.

With repeal of the MCIT rule, and no alternative defined pathway for Medicare coverage of many innovative medical device treatments, patients will continue to wait too long or must pay out of pocket for many noninvasive treatments like focused ultrasound. We know that CMS is committed to helping patients, reducing suffering, improving outcomes, and saving lives, and we are eager to see a new rule that closes the current gap between FDA clearance and Medicare coverage.

Thank you for your consideration. We strongly urge CMS to establish a new rule as soon as possible and to continue to work with medical technology innovators, healthcare providers, patients, and others to improve and expedite the path from FDA marketing authorization to CMS coverage. Patients deserve more timely and equitable access to breakthrough treatments.

If you have questions, please do not hesitate to contact me at jfoley@fusfoundation.org or 202.886.5300.

Sincerely,



Jessica Foley, PhD
Focused Ultrasound Foundation