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October 30, 2020

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3372-P  
P.O. Box 8013  
Baltimore, MD, 21244-8013

RE: CMS-3772-P, Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"

Dear Administrator Verma:

We appreciate the opportunity to comment on the CMS proposed rule on the "Medicare Coverage of Innovative Technology (MCIT)" program.

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 patient access to focused ultrasound therapies, and other highly innovative medical device technologies, is the lag time between FDA approval 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.

With this new MCIT pathway, CMS is proposing to 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 proposed MCIT pathway would eliminate the gap between FDA approval and Medicare coverage for innovative medical devices, providing more certainty to manufacturers, more tools in clinicians’ armamentarium to treat disease, and more universal treatment options for patients. The proposed four-year provisional coverage period would be sufficient to enable acquisition of any further clinical evidence to support a long-term National Coverage Decision (NCD) or Local Coverage Decisions (LCD).

As proposed, only devices that have received breakthrough designation by the FDA would be eligible for the MCIT program. While only a small number of devices have received breakthrough marketing authorization by the FDA, there are many other promising innovative devices that may not meet the stringent definitions for breakthrough (e.g. for a serious medical condition that does not meet the threshold for life-threatening or debilitating) or were approved before the implementation of the Breakthrough pathway yet still lack CMS coverage. We urge CMS to expand the criteria for acceptance to the MCIT program to include more universal coverage of noninvasive medical devices including focused ultrasound that may be strongly preferred by patients as compared to more invasive alternatives. We encourage CMS to consider “patient preference” as an optional criterion to support acceptance into the MCIT program.

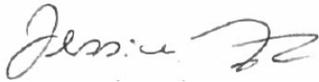
Additionally, we encourage the coverage of off-label use of devices accepted to the MCIT program. For many innovative medical technologies such as focused ultrasound, a single device could have several clinical applications. For example, a prostate-specific device could be effective treating both prostate cancer and benign prostatic hyperplasia. FDA labeling of the device in this case is often more generic – i.e. prostate tissue ablation. Such a general label may not meet the strict requirements for breakthrough despite having a similar or greater impact on the lives of patients as other breakthrough devices. In a case such as this, we propose that the MCIT program should provide coverage for an off-label indication (e.g. prostate cancer) that meets the breakthrough designation criteria provided there is clinical evidence to support its safety and efficacy.

Coding and payment should also be considered in the implementation of the finalized MCIT rule. It is preferable that coding and payment be linked to coverage for devices within the MCIT program. Many medical treatments obtain CMS coverage yet still are limited by low reimbursement rates and/or lack an appropriate code. Widespread adoption of innovative medical device therapies requires adequate coding, coverage and reimbursement. Without all three components in place at the start of the four-year coverage window, the MCIT program may not have its full intended effect for all breakthrough devices.

Finally, we would not support CMS automatically opening a national coverage analysis if a MAC has not issued an LCD for a breakthrough device within 6 months of the expiration date of the four-year MCIT period. This timeframe may not be sufficient to allow for completion of any ongoing evaluation process by an LCD(s).

Thank you very much for consideration of our comments. If you have questions, please do not hesitate to contact me at [jfoley@fusfoundation.org](mailto:jfoley@fusfoundation.org) or 202.886.5300.

Sincerely,

A handwritten signature in black ink, appearing to read "Jessica Foley". The signature is fluid and cursive, with a large, stylized initial "J" and "F".

Jessica Foley, PhD  
Focused Ultrasound Foundation