

June 25, 2021



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

Dear Centers for Medicare & Medicaid Services,

Thank you for giving us the opportunity to comment on the Medicare Program: Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" – CMS-3372-IFC, and specifically whether the revisions in the MCIT final rule adequately addressed the public's concern of clinical benefit to the Medicare population.

As you know, the medical technology community produces life-saving and life-enhancing medical devices, diagnostic products, and health information systems. This technology transforms health care through earlier disease detection, less invasive procedures, and more effective treatments. These advancements come from the largest to the smallest medical technology innovators and companies.

Thousands of medical solutions lag for up to three years between FDA approval and CMS coverage which puts companies out of business and denies patients the care they need. Access to state-of-the-art medical technology and diagnostics can enhance patient care delivery options and improve outcomes. However, even if a groundbreaking and innovative technology meets FDA's rigorous standards for expedited review and is ultimately cleared or approved, significant hurdles remain because FDA approval does not automatically grant coverage and payment under Medicare. This results in delayed access for Medicare patients to life-saving technologies that the FDA has deemed to be not just safe and effective but a breakthrough.

We need to recognize that if doctors and scientists at the FDA - the global gold standard for medical technology regulation - determine a device is safe and effective, then another federal agency can move quickly to ensure patients can access that life-changing and often life-saving technology.

Thank you for your consideration. We strongly encourage you to establish the MCIT program as soon as possible to ensure patients obtain the care they need and are given the best chance of a full recovery.

Sincerely,

A handwritten signature in black ink, appearing to read "John F. Lewis, Jr.", written in a cursive style.

John F. Lewis, Jr.
President & CEO
BioOhio