October 13, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P2
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) Repeal- CMS-3372-P2

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) Repeal – CMS-3372-P2.

On behalf of BioOhio, its Board of Trustees, and our nearly 300 members that employ over 100,000 Ohioans, I write to you today to encourage the establishment of rules to support the medical technology community to incentivize access to breakthrough technologies in lieu of MCIT. Patients' lives will be held in the balance without a replacement rule or an expedited coverage pathway to access breakthrough innovations. Our goal in this country should be to encourage, not inhibit, innovations that will change patients' lives. We hope the repeal of MCIT will spark new conversations on ensuring life-saving technologies reach patients who need them most.

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 both established and growing 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 technology meets the 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 also a breakthrough. Any patient and doctor who has exhausted all existing medical options should have immediate access to FDA-approved breakthrough medical technologies.

We strongly encourage you to establish rules to establish an expedited coverage pathway as soon as possible to ensure doctors and patients can access the care they need for the best chance of a full recovery and life.

We welcome the opportunity to work on best practices and policies to expand patient access to beneficial breakthrough technologies. We appreciate your consideration.

Sincerely

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President & CEO, BioOhio

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