

October 14, 2021

The Honorable Chiquita Brooks-LaSure
Administrator of the Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mailstop C4-26-05
7500 Security Blvd. Baltimore, MD 21244-1850

Re: Proposed Rule to Repeal the Medicare Coverage of Innovative Technology (MCIT) implementation (CMS-3372-P2)

Submitted electronically

Dear Administrator Chiquita Brooks-LaSure:

On behalf of BloodPAC, I am writing to oppose the repeal of the MCIT final rule. BloodPAC has previously submitted comment letters supporting the implementation of the MCIT pathway to facilitate beneficiary access to life saving technologies, particularly blood based molecular diagnostic tests.

Originally established as a commitment to under the White House Cancer Moonshot, BloodPAC is independent public-private consortium with a mission to accelerate the development, approval and accessibility of liquid biopsy assays to improve the outcomes of patients with cancer. We do this via an unprecedented collaborative consortium infrastructure of over 50 members comprised of industry, academia, non-profits and regulatory agencies. Together, we develop standards and best practices, organize and coordinate research studies through our members, and operate a data commons to support the broader liquid biopsy research community.

We know that advanced diagnostic tests, and blood-based ones in particular, are critical to guiding physicians in making the most informed treatment decisions for patients with cancer. BloodPAC strongly encourages CMS to implement the Final Rule and establish the MCIT pathway, which will significantly and immediately improve beneficiary access to devices that have received breakthrough designation.

The repeal of the Final Rule hampers the evidence development for these innovative devices in the Medicare population by creating uncertainty around the coverage environment for Medicare beneficiaries. Should the MCIT final rule be repealed, we urge CMS to pursue new proposed rulemaking at the same time of the repeal so the process may resume without delaying access to novel technologies.

Respectfully,



Lauren C. Leiman
Executive Director
BloodPAC

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