BloodPAC
BLOOD PROFILING ATLAS IN CANCER

April 16, 2021

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

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary''; Delay of Effective Date; Public Comment Period (CMS–3372–IFC)

Submitted electronically

Dear Acting Administrator Richter:

On behalf of BloodPAC, we write in support of the implementation of the Final Rule establishing the Medicare Coverage of Innovative Technology (MCIT) pathway to facilitate beneficiary access to life saving technologies and offer the below responses to questions raised by the agency in the Interim Final Rule (IFR).

BloodPAC is a public-private consortium that develops standards and best practices, organizes and coordinates research studies through its members, and operates a data commons to support the liquid biopsy research community. Data from retrospective studies run by members, as well as studies BloodPAC organizes, are aggregated and contributed to the BloodPAC Data Commons (BPDC) to establish an open, publicly accessible data commons for the global liquid biopsy community.

Our mandate at BloodPAC is 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 45 members comprised of industry, academia, and regulatory agencies. 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 suffering from cancer.

BloodPAC strongly encourages CMS to implement the Final Rule and establish the MCIT pathway, which will significantly improve beneficiary access to FDA-cleared or approved

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devices that have received breakthrough designation based on a FDA determination that these devices "may provide better health outcomes for patients facing life-threatening or irreversibly debilitating human disease or conditions."

I. Recommendations for Operationalizing Coverage

a. Benefit Category Determination

BloodPAC appreciates the agency's confirmation in implementing the Final Rule that the MCIT pathway "includes any clinical lab diagnostic test, including in-vitro diagnostics…as long as it meets the MCIT eligibility criteria". BloodPAC believes the MCIT Final Rule made it clear that Medicare should establish coverage for items and services outlined at §405.603, services that fall within a benefit category under the scope of Part A or B benefits when making the benefit category determination, we encourage CMS to continue to include all benefit categories for consideration as this is in line with the goals of the MCIT pathway.

b. Relevant Coding and Payment Procedures

BloodPAC feels that there are existing coding and payment pathways in the Medicare program to accommodate MCIT-eligible technologies. Current examples of the inpatient new technology add-on payment (NTAP) process and the hospital outpatient transitional pass-through payment (TPT) process, specifically allow for quarterly code creation for select technologies. In addition there is experience via investigational device exemption (IDE) studies for coding, payment and benefit categories for breakthrough technologies. The Technology, Coding, and Pricing Group was established by CMS to coordinate among coverage, coding, and payment processes for innovative technologies, including breakthroughs. As CMS acknowledges, it can take months from designation of a breakthrough device to authorization, allowing for time for the manufacturer to work with CMS.

Thank you again for the opportunity to comment on the Medicare Coverage of Innovative Technology (MCIT) pathway.

Respectfully,

Lauren C. Leiman
Executive Director
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