BloodPAC
BLOOD PROFILING ATLAS IN CANCER

November 2, 2020

Ms. Linda Gousis
Ms. JoAnn Baldwin
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244--8013

Re: File Code CMS-3372-P
Medicare Coverage of Innovative Technology and Definition of "Reasonable and Necessary"
Submitted electronically

Dear Ms. Gousis and Ms. Baldwin:

On behalf of BloodPAC, we thank you for the opportunity to provide comments on the Federal Register document citation number 42 CFR Part 405, which announces the proposed rule on Medicare Coverage of Innovative Technology (MCIT) and Definition of "reasonable and necessary."

BloodPAC introduction
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 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.

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We applaud the agency's proposal to streamline the approval, coverage, and coding process of breakthrough medical devices. This letter addresses a few of the questions posed in 42 CFR Part 405, specific to Establishing the MCIT pathway for breakthrough devices.

Introduction

We applaud the recognition of Medicare beneficiaries' unmet medical needs and willingness to coordinate with the FDA to facilitate access to breakthrough devices. BloodPAC supports the proposed rule to establish a voluntary MCIT pathway which provides coverage for breakthrough devices, upon the date of FDA market authorization for up to four years. This letter addresses a few of the key questions posed in 42 CFR Part 405.

- **Eligible MCIT Pathway Devices:** The final rule should include diagnostics under the list of approved devices. The FDA definition of medical device includes diagnostics, and diagnostics have received breakthrough device approvals.
- **MCIT Program Duration:** Four years is an appropriate duration to provide coverage, while allowing manufacturers to develop clinical evidence and demonstrate the utility of these new technologies in the marketplace. BloodPAC also asks that CMS evaluates retroactive coverage of devices approved (prior to finalization of MCIT) with caution: recognizing the need to balance equity in coverage and evidence development with overall program costs.
- **Opt-In Approach**: Laboratories and manufacturers should be required to opt-in to MCIT. Issues around evidence development and coverage planning may be complex – and the staff investments must be comparable between CMS and the impacted provider(s).
- **CMS should not require manufacturers to provide data about outcomes nor be obligated to enter into a clinical study similar to CMS' Coverage with Evidence Development (CED):** BloodPAC believes that manufacturers will engage with CMS on coverage pathways and study designs that address unique gaps in clinical utility for liquid biopsy assays. However, these decisions should be made specific to the requirements of each device and its potential coverage path, and a single approach could stifle intended results.
- **CMS should ask device manufacturers to declare an intended CMS coverage pathway (if contractors have not issued LCDs for breakthrough device within 6 months of the 4-year MCIT expiration);** Alignment on this pathway (whether LCD, NCD, or no coverage) ensures clarity for all parties. Misalignment could negatively impact commercialization plans for the intended device(s) – and also for competitive devices which may be pursuing a similar local or national coverage path with CMS, regardless of (their) breakthrough designation status.

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

Respectfully,

Lauren C. Leiman
Executive Director
BloodPAC

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