



September 1, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Calendar Year (CY) 2023 Medicare Physician Fee Schedule Proposed Rule
Submitted electronically

Dear Administrator Brooks-LaSure:

On behalf of BLOODPAC, thank you for the opportunity to review and comment on the Calendar Year 2023 Proposed Physician Fee Schedule.

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.

We define a liquid biopsy as a molecular test performed on a sample of blood, urine, or other body fluid, to look for signals associated with cancer, such as circulating tumor cells, DNA, RNA, or proteins.

Liquid biopsy use cases vary, and may include:

- (a) detecting cancer at an early stage
- (b) informing treatment with targeted therapies, based on presence or absence of specific mutations
- (c) determining treatment efficacy and/or cancer recurrence (e.g., relapse or minimum residual disease)

Our mandate at BLOODPAC is to accelerate the development, approval and accessibility of liquid biopsy assays to improve the health outcomes of patients with cancer. We do this via an unprecedented collaborative consortium infrastructure of over 60 members comprising industry, academia, and regulatory agencies.

We applaud the efforts of CMS to expand coverage of colorectal cancer screening and reduce barriers to care. Our comments will focus on two areas in the proposed rule: changes to the minimum age payment limitation; and eligibility for coverage without cost-sharing of a follow-up colonoscopy after a positive non-invasive guideline recommended test.

BLOODPAC supports CMS' proposal to expand Medicare coverage of certain CRC screening tests by lowering the minimum eligible age to 45 years

We support this proposal, which aligns with updated colorectal cancer (CRC) screening recommendations from the United States Preventive Services Task Force (USPSTF), the American Cancer Society (ACS), and other guideline developers.

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BLOODPAC also thanks CMS for including one testing category that was omitted from the USPSTF recommendation: blood-based biomarker tests. These are Medicare-covered screening tests (described in NCD 210.3) and serve as an emerging alternative to direct visualization and stool-based tests. Consistency of coverage and payment in CRC screening policies improves clarity among all constituents, and drives meaningful gains in both early detection and health outcomes – particularly among beneficiaries whose access to these critical medical services may be otherwise hindered.

BLOODPAC seeks parity among Medicare-covered CRC screening tests, whether blood- or stool-based

CMS also proposes to enhance coverage of CRC screening tests by including a follow-on screening colonoscopy at no cost sharing for the patient after a “Medicare-covered non-invasive stool-based CRC screening test” returns a positive result.

When proposing to lower the minimum age requirement for CRC screening, CMS included blood-based screening tests, noting that blood-based CRC screening was covered within NCD 210.3. We note extending eligibility for a follow-on screening colonoscopy (after a positive blood-based test) was not reflected in the current proposal by CMS.

BLOODPAC supports this provision, but recommends that CMS extend this policy to cover a follow-on screening colonoscopy after a positive guideline recommended blood-based testing result. A positive Blood-based CRC screening test will also require a follow-up colonoscopy.

The consequences of inconsistency are significant, in terms of policy application and beneficiary cost sharing:

1. CMS proposes to waive the frequency limitations for CRC tests and follow-on screening colonoscopy when furnished as part of the new CRC screening benefit.
2. Beneficiary cost sharing for the initial screening test and confirmatory screening colonoscopy would not apply, as Medicare payment would fully cover these costs.

These requested changes would advance the Agency’s goal of consistent coverage and payment policies and serve to promote access to CRC screening among Medicare beneficiaries.

Thank you again for the opportunity to review and comment on the 2023 Proposed Physician Fee Schedule. We welcome the chance to further engage with CMS to discuss concerns and tools to ensure these policies are adopted and well understood among the clinical laboratory community.

Should you have additional questions or require our expertise, please direct your correspondence to me at lauren@BLOODPAC.org.

Respectfully,

A handwritten signature in black ink that reads 'Lauren C. Leiman'.

Lauren C. Leiman
Executive Director
BLOODPAC

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