

July 15, 2021

Ms. Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2022**

*Submitted electronically:*

[CLFS\\_Annual\\_Public\\_Meeting@cms.hhs.gov](mailto:CLFS_Annual_Public_Meeting@cms.hhs.gov)

Dear Administrator Brooks-LaSure:

On behalf of BloodPAC, we respectfully submit comments for consideration to CMS regarding the recently held CY 2022 Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting on June 24, 2021.

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 clinical studies performed 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 nearly 50 members comprising industry, academia, nonprofits and regulatory agencies. We believe 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 provides the following comments regarding **G0327 “Colorectal cancer screening; blood-based biomarker.”**

In May 2021, CMS announced that contractors shall recognize HCPCS code G0327 to facilitate the reporting of blood-based biomarker tests covered under the January 2021 revision to National Coverage Determination (NCD) 210.3 for colorectal cancer (CRC) screening.<sup>1</sup> BloodPAC acknowledges and appreciates the effort by CMS to facilitate claims processing for novel blood-based CRC screening assays that meet the coverage criteria set forth in the NCD. At this time, however, there are a number of procedural and mitigating factors which make it premature for CMS to consider the addition of G0327 to the CY2022 CLFS:

- There was inadequate notice for stakeholders to provide a presentation or comments regarding the code at the Public Meeting on June 24, 2021. CMS did not add G0327 to the Public Meeting agenda until June 21, 2021, well after the registration deadline for the Public Meeting. Interested stakeholders were not given adequate notice to prepare comments or otherwise meaningfully participate in the statutorily-prescribed rate-setting process for G0327.<sup>2</sup>
- Currently, there are no blood-based biomarker tests for colorectal screening that meet the criteria for coverage under the NCD. This would mean CMS lacks necessary information to establish pricing, setting both a dangerous precedent and a significant burden on policymakers.
- Under the crosswalk process, one option for pricing a new or revised code, CMS determines whether the test is “comparable” to an existing test, multiple existing test codes, or a portion of an existing test code.<sup>3</sup> However, there are no applicable tests to use for crosswalking G0327.
- Likewise, if CMS were to consider the alternate option (i.e., gapfill) for G0327, the Medicare Administrative Contractors (MACs) are asked to consider:
  - charges for the test and routine discounts to charges
  - resources required to perform the test
  - payment amounts determined by other payers

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<sup>1</sup> Transmittal 10818 (Change Request 12280) (May 20, 2021), <https://www.cms.gov/files/document/r10818cp.pdf>.

<sup>2</sup> 42 C.F.R. § 414.506 - Federal Register / Vol. 86, No. 83 / Monday, May 3, 2021 pg 23386

<sup>3</sup> 42 C.F.R. § 414.508(b)(1).

- charges, payment amounts and resources required for other tests that may be comparable or otherwise relevant, and
- other criteria that CMS determines appropriate.

These data do not exist, and are not available to the MACs so gapfilling G0327 is not possible.

- CMS has not addressed whether the intent is for all blood-based CRC screening assays to be reported with HCPCS code G0327, or if test developers may report assays with procedure codes (e.g., PLA or CPT codes) specific to their actual design.
- Finally, BloodPAC contends that it is inappropriate and sets a dangerous precedent to assign one single code and set a single rate for all tests that may qualify for coverage under the NCD for the following reasons:
  - As stated above, no such test currently exists.
  - Even when such a test becomes commercially available, CMS should not set a rate for all such tests based on information (e.g., charges, payment amounts and resources) applicable to a single test.

BloodPAC looks forward to additional dialogue regarding the CY2022 CLFS rate setting process, and we are happy to answer any questions and to provide additional information.

Respectfully,



Lauren C. Leiman  
Executive Director  
BloodPAC