

November 11, 2021

National Government Services (NGS)
Medical Policy Unit
P.O. Box 7108
Indianapolis, IN 46207-7108
PartBLCDCComments@anthem.com

Re: Public Comments for Proposed Local Coverage Determination, “Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (DL37810)” and Draft Article “Billing and Coding: Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (DA56867)”

Submitted electronically

Dear National Government Services:

On behalf of BloodPAC, thank you for the opportunity to submit public comments regarding the proposed Local Coverage Determination (LCD) “Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (DL37810)” and Draft Article “Billing and Coding: Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (DA56867).”

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 health outcomes of patients with cancer. We do this via an unprecedented collaborative consortium infrastructure of over 50 members comprising industry, academia, and regulatory agencies.

We applaud the efforts of National Government Services to expand coverage and access to comprehensive genomic profiling for appropriate Medicare beneficiaries, and wish to share the following comments:

1. The draft LCD excludes circulating tumor DNA testing (ctDNA). We ask that this sample type be included under this LCD when it is being used as a “liquid biopsy” to inform the use of targeted therapy in advanced cancer patients. Coverage for this additional sample type (plasma) would require similar assay performance (analytical validity) and essential biomarker content, as per medical guidelines.

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2. Please remove the requirement “CGP NGS testing for patients with advanced cancer is reasonable and necessary only when more limited (e.g. individual analyte or targeted panel (5-50 genes)) testing is insufficient.” We request that this requirement be removed as there are several reasons a physician may decide to order a CGP test over an individual analyte or targeted panel test such as:
 1. limited tissue availability or
 2. to assess tumor mutational burden (TMB) to identify the use of immunotherapy (e.g. pembrolizomab); TMB requires the sequencing of hundreds of genes to obtain a reliable measurement.
3. The draft Billing and Coding Article does not list all of the applicable billing codes specific to comprehensive genomic profiling tests that would meet the coverage criteria. We ask that National Government Services provide a mechanism for codes associated with tests that meet the coverage criteria to be included.
4. In lieu of the draft LCD requirement for coverage when there are “published peer-reviewed studies supporting analytic validity,” we ask that NGS also considers accepting the comprehensive process used in the New York State Department of Health (NYSDOH) approval process to evaluate and to approve Lab Developed Tests (LDTs) using next generation sequencing testing of molecular tumor markers as a reliable indication of a test’s analytical validity and sensitivity. The Wadsworth Center’s Clinical Evaluation Program (CLEP) requires extensive, detailed information about a test’s validation studies including: analytic sensitivity, accuracy, precision, reproducibility and the test’s performance characteristics for each sample type. BloodPAC believes these criteria are more than sufficient to determine a CGP test’s performance characteristics for NGS.

Respectfully,



Lauren C. Leiman
Executive Director
BloodPAC