BLOODPAC

July 22, 2022

First Coast Service Options, Inc.
Medical Affairs
2020 Technology Parkway
Suite 100
Mechanicsburg, PA 17050
ProposedLCDComments@fcso.com

Novitas Solutions, Inc.
Medical Affairs
2020 Technology Parkway
Suite 100
Mechanicsburg, PA 17050
ProposedLCDComments@novitas-solutions.com

RE: Genetic Testing for Oncology – DL39367 (First Coast) and DL39365 (Novitas)
Submitted electronically

Dear Medical Directors:

On behalf of BLOODPAC, thank you for the opportunity to review and comment on First Coast and Novitas' proposed coverage policy for Genetic Testing for Oncology (DL39367 and DL39365).

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 60 members comprising industry, academia, and regulatory agencies.

We applaud the efforts of Novitas and FCSO to revise coverage of its genetic testing policies, and submit the following comments to better understand its intent:

1. Does Novitas/FCSO intend to replace the longstanding policy, entitled "Biomarkers in Oncology" (L35396), with "Genetic Testing for Oncology (DL 39367 and DL 39365)?

2. The draft article (Billing and Coding: Genetic Testing for Oncology - DA59125) notes specific PLA codes for test coverage within the liquid biopsy space (e.g., 0179U), though several CLIA labs offer ctDNA assays (molecular assays with a liquid specimen) that bill through traditional GSP codes (81445, 81455.)

   (a) May we assume the plasma specimen type will be covered by Novitas/FCSO, if all other facets of coverage parameters have been sufficiently addressed (e.g., demonstrated Analytic Validity, Clinical Validity, Clinical Utility; adherence to CPT policy descriptor?)

   (b) Would assay coverage also require alignment to corresponding guidelines (e.g., NCCN Guidelines version 3.2022 – Non-Small Cell Lung Cancer: Principles of Molecular Analysis?)

20 West Kinzie Street
Chicago, Illinois 60654
info@BLOODPAC.org
www.BLOODPAC.org

BLOODPAC

3. Do you envision the creation and routine maintenance of a database that allows CLIA labs to correctly interpret the biomarkers, procedural (CPT/PLA), and diagnostic code (ICD-10) implications of the chosen three database/knowledge bases: ClinGen, NCCN, and OncoKB?

4. The draft LCD's "Limitations" section notes "…following are considered not medically reasonable and necessary: A genetic test where either analytical validity, clinical validity, or clinical utility has not been established." How will these criteria be determined?

5. Specific to Billing and Coding: Genetic Testing for Oncology (DA59125). Also under "Limitations," the policy highlights "Repetitions of the same genetic test on the same genetic material" would not be covered. When considering MRD (minimum residual disease) testing applications, please clarify whether "same genetic material" will be determined by specimen, date of service, and/or CPT codes.

6. Under the proposed LCD's coverage guidance section (Covered Indications) limitations, the draft determination notes testing is not reasonable and necessary when (3) *"Genetic testing in patients who do not have either an established diagnosis of cancer or substantiated suspicion of cancer as determined by a clinical evaluation and abnormal results (cancer or suspicious for cancer) from histologic and/or cytologic examination."*

   Certain advanced cancer patients may not be candidates for tissue biopsy due to a high risk of complications, or the location of tumor(s) may preclude a tissue biopsy. In that case, diagnosis and staging may be established through imaging alone. Predicitve biomarker testing may still be recommended and, likely, performed through liquid biopsy. The requirement that histologic and/or cytologic examination be performed as a prerequisite for critical genomic tests may hinder coverage of ctDNA biomarker testing for a population of cancer patients not eligble for tissue biopsies. We ask that you reconsider and rephrase this limitation.

Thanks again for the opportunity to review and comment on this proposed policy. We welcome the chance to further engage with FCSO and Novitas to discuss procedural concerns, resources available to distinguish issues around test performance and utility, 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,

Lauren Leiman

Lauren C. Leiman
Executive Director
BLOODPAC

20 West Kinzie Street
Chicago, Illinois 60654
info@BLOODPAC.org
www.BLOODPAC.org