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September 8, 2023

Dr. Patrick Mann, M.D.
Contractor Medical Director
Novitas Solutions Medical Affairs
2020 Technology Parkway, Ste. 100
Mechanicsburg, PA 17050

Dr. Juan Schaening, M.D
Executive Contractor Medical Director
First Coast Service Options, Inc.
532 Riverside Avenue
Jacksonville, FL 32202

RE: Genetic Testing for Oncology – Public Comment
Submitted via email to
ProposedLCDComments@fcso.com
ProposedLCDComments@novitas-solutions.com

Dear Drs. Mann and Schaening:

On behalf of BLOODPAC, thank you for the opportunity to review and comment on draft local coverage determination (LCDs) DL39367 and DL39365: Genetic Testing for Oncology.

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:

- Detecting cancer at an early stage
- Informing treatment with targeted therapies, based on presence or absence of specific mutations
- Determining treatment efficacy and/or cancer recurrence (e.g., relapse or minimum/molecular 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.

Specific to draft LCDs DL 39365 and DL39367, we are concerned that current language will severely limit Medicare beneficiaries' access to medically necessary diagnostic tests. This letter focuses on the omission of critical ICD-10 codes listed in the corresponding billing/coding articles (DA59123 and DA59125, respectively).

While the list of associated ICD-10 codes connected with somatic biomarker testing via Next Generation Sequencing (CPT/PLA codes cited in Groups 7-9) seems extensive – these ICD-10 lists exclude a vital set of codes frequently used in advanced cancer care: "unspecified" codes.

Two examples, specific to non-small cell lung and breast cancers, respectively, include:

- C34.90 – Malignant neoplasm of unspecified part of unspecified bronchus or lung
- C50.919 - Malignant neoplasm of unspecified site of unspecified female breast

By restricting coverage for these and other ICD-10 codes, a significant percentage of Medicare beneficiaries with advanced cancers would face barriers to genomic testing of their tumors/plasma. We urge Novitas and First Coast to query your own patient data to determine its potential impact.

From a clinical perspective, we offer several comments to support this request:

- These ICD-10 codes are frequently used in testing for molecular patients where the precise location in the organ of the primary cancer is not definitive.
- It is also appropriate for post-surgery patients with recurrent disease (e.g., double mastectomy patients) when location-specific coding is no longer applicable.
- The primary tumor typically cannot be determined in non-small cell lung cancer patients who present with multiple tumors in both lungs.
- Cancers of the digestive system may be so extensive that it is impossible to determine their primary site.
- Patients with advanced tumors will often be treated with systemic therapy and defining the laterality of the tumor via a more specific ICD-10 code is irrelevant.

There are multiple CMS policy examples where such ICD-10 code use is recommended, demonstrating that CMS understands our concern that "not otherwise specified" (NOS) codes are needed for billing in certain cases:

First, the 2023 ICD-10 CM Official Guidelines for Coding and Reporting (updated April 1, 2023) notes "Sign/symptom and "unspecified" codes have acceptable, even necessary, uses. While specific diagnosis codes should be reported when they are supported by the available medical record documentation and clinical knowledge of the patient's health condition, there are instances when signs/symptoms or unspecified codes are the best choices for accurately

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reflecting the healthcare encounter. Each healthcare encounter should be coded to the level of certainty known for that encounter."[1]

Additionally, we applaud the agency for listening to public comments during rulemaking in August 2021 and acknowledging that the "laterality affected might be difficult to determine in certain instances" involving neoplasms[2]. In this regulatory action as part of the FY 2022 IPPS Final Rule, CMS decided to leave out numerous cancer ICD-10 NOS codes from designation changes to not discourage their use in the inpatient setting. Since CMS has now affirmed that these ICD-10 NOS codes remain valid and appropriate for other services for the same cancer patients, the decision to exclude these codes from this LCD does not appear to be consistent with CMS's intention.

Further evidence that CMS intends to cover ICD-10 codes with unspecified locations is evidenced in the transmittals for NCD 90.2. All the covered services in 90.2 include the unspecified ICD-10 codes[3]. We also remind you that, per OIG guidance on laboratory compliance from 1996[4], CLIA labs are not able to change ICD-10 codes, nor can they lead ordering physicians to issue a code that improves coverage scenarios. At the time of test order, beneficiaries have already been diagnosed with advanced cancer and assigned ICD-10 code(s) by their team of treating physicians. Since providers frequently use these unspecified ICD-10 codes for other services for their cancer patients, disallowing these unspecified codes specifically for laboratory testing will not minimize the utilization of unspecified codes; it will unfortunately just limit access to next-generation sequencing (NGS) testing for these advanced cancer patients.

Finally, we also urge consideration of adding a second, distinct list of ICD-10 codes to billing/coding articles DA59123 and DA59125: these represent codes frequently used in molecular/minimal residual disease (MRD) testing. Two prominent examples include:

- Z85.038 - Personal history of other malignant neoplasm of large intestine

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[1] Centers for Medicare & Medicaid Services (U.S.) "ICD-10-CM official guidelines for coding and reporting FY 2023 - UPDATED April 1, 2023 (October 1, 2022 - September 30, 2023)" (2023)
[2] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program. 86 FR 44774. (2021)
[3] https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR13278.zip
[4] https://oig.hhs.gov/documents/compliance-guidance/965/cpcl.html
[5] https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58376&ver=32&keyword=mrd&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

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- Z85.51 - Personal history of malignant neoplasm of bladder

For reference, the corresponding MolDX article lists almost 50 ICD-10 codes, specific to several different indications[5].

On behalf of BLOODPAC, we urge Novitas and First Coast to address these issues and not finalize the LCD/Article as drafted.

We appreciate your consideration of our comments. Should you have any questions or require our expertise, please direct your correspondence to me at lauren@BLOODPAC.org.

Respectfully,

Lauren C. Leiman
Executive Director
BLOODPAC