September 8, 2023

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

Dr. Alicia Campbell, MD
Contractor Medical Director
First Coast Service Options, Inc.
P. O. Box 3425
Mechanicsburg, PA 17055

RE: Local Coverage Determination "Genetic Testing for Oncology" (DL39365, DL 39367)

Dear Dr. Mann and Dr. Campbell,

On behalf of the undersigned diverse stakeholder organizations, we are writing to express our concerns about the draft local coverage determinations (LCDs) entitled "Genetic Testing for Oncology," issued by Novitas and First Coast Service Options (FCSO).[1] We fear that if the LCDs are finalized as drafted, Medicare beneficiaries with cancer will lose access to clinically appropriate genetic testing – and their treatment teams will lose access to critically important tools for diagnosing and managing the Medicare beneficiaries' conditions. Furthermore, the policies appear not to comply with requirements for issuing LCDs, as set forth in the Social Security Act and the Medicare Program Integrity Manual. We urge you not to finalize the LCDs as drafted.

We are deeply concerned about the draft LCDs' "default" non-coverage for genetic tests that are not included on one of three knowledgebases.[2] We understand that a provider, organization, or Medicare beneficiary could submit a reconsideration request so that a non-covered test potentially could be included in the LCDs, but that could take a significant amount of time and prevent meaningful access to a test when a beneficiary is in the midst of a cancer diagnosis. It is not clear how long the LCD reconsideration process may take or whether Novitas and FCSO will prioritize reconsideration requests in any way. Timely access to diagnostics that inform treatment decisions is critical for all patients, especially those with cancer, and we worry that the presumptive non-coverage approach will harm the Medicare beneficiaries to whom we represent or provide care.

Beyond the non-coverage issues, we have strong concerns that the draft LCD and accompanying draft Billing and Coding Article will impede patient access to appropriate tests that are included in the knowledgebases. For example, the accompanying billing articles do not include

[1] DL39365, *available at* https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39667&ver=9&keyword=&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=updated&bc=1; DL 39367, *available at* https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39668&ver=8&keyword=&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=updated&bc=1.

[2] ClinGen (National Institutes of Health), NCCN Compendium (National Comprehensive Cancer Network), and OncoKB (Memorial Sloan Kettering Cancer Center).

several of the ICD-10 codes that are included in current LCDs covering this area, and Novitas and FCSO have not explained this change. If an ICD-10 code is not in the billing article, it is considered to not support the medical necessity of testing and the test will not be covered. This appears to be another limitation that will have an adverse effect on beneficiary access to appropriate genetic testing. In one instance, "not otherwise specified" codes have not been included in the draft LCDs. To be sure, it is important for a treating health care practitioner to select the most specific diagnosis code possible – yet in some circumstances, a "not otherwise specified" code is the appropriate code. Two other sets of codes that have not been included are those that describe remission and a personal history of cancer. The exclusion of the remission codes and the personal history of cancer codes will prevent genetic testing to monitor a condition, such as minimal residual disease testing (MRD), and to establish remission for hematological malignancies; DNA testing that otherwise may be covered under the draft LCDs. Novitas and FCSO should explain why they have categorically excluded these types of ICD-10 codes.

Beyond the coding issue, there are many issues in the draft LCD that will prevent coverage of appropriate tests for Medicare beneficiaries. We are greatly concerned about the potential negative impact this policy will have on appropriate reflex testing and the extensive "Documentation Requests" that we expect will limit coverage, due to documentation and information sharing difficulties between the ordering provider and the laboratory. Additionally, the draft policies limit genetic tests for hereditary cancer syndromes, which are considered germline testing, to once per beneficiary's lifecyce, regardless of advances in technology, improved tests, and the vastly expanded list of known variants and their implications for a patient's health.

As we know you have heard from other stakeholders, we do not believe that Novitas and FCSO have issued draft LCDs that meet the regulatory requirements for an LCD as established by Congress and implemented by the Centers for Medicare & Medicaid Services (CMS). 42 U.S.C. § 1395y(l)(5)(D) requires Medicare contractors to include a summary of evidence considered by the contractor when developing an LCD. But in the draft LCDs, Novitas and FCSO include only an evaluation of the *knowledgebases* whose sponsors presumably have considered evidence regarding genetic testing. While the three knowledgebases offer valuable guidance, they do not include the full range of oncology testing that may be reasonable and medically necessary for a Medicare beneficiary, which may limit beneficiaries' access to testing. While the knowledgebases provide opportunities for the public to provide input, that does not relieve a Medicare contractor from conducting an independent review of the available evidence regarding the use of an item or service in the Medicare population and to use notice-and-comment procedures and process for their coverage decisions.

Our united organizations are focused on expanding access to medically necessary genetic testing for oncology and we fear that this coverage policy will be a step in the wrong direction. **We urge Novitas and FCSO to work with stakeholders to address the significant concerns raised in this letter.** Medicare beneficiaries would be better served by policies developed in compliance with the requirements for issuance of LCDs and that would not severely curtail access to valuable genetic tests used in the diagnosis and management of cancers. Thank you very much for your consideration of our comments.

Sincerely,

Advanced Practitioner Society for Hematology and Oncology
AliveAndKickn
American Cancer Society Cancer Action Network
American Clinical Laboratory Association
American College of Medical Genetics and Genomics
American Gastroenterological Association
American Society for Clinical Pathology
American Society for Radiation Oncology
Association for Molecular Pathology
Association of Community Cancer Centers
Biomarker Collaborative
Bladder Cancer Advocacy Network (BCAN)
Blood Profiling Atlas in Cancer (BLOODPAC)
Cancer Support Community
Cancer Support Community Delaware
Cancer Support Community Greater Lehigh Valley
Cancer*Care*
Caregiver Action Network
Cholangiocarcinoma Foundation
College of American Pathologists
Community Liver Alliance
FORCE: Facing Our Risk of Cancer Empowered
Free ME from Lung Cancer
GI Cancers Alliance
Gilda's Club South Florida, Inc.
GO2 for Lung Cancer
ICAN, International Cancer Advocacy Network
Living Beyond Breast Cancer
Lung Cancer Research Foundation
LUNGevity Foundation
MET Crusaders
National Alliance of State Prostate Cancer Coalitions
National Marrow Donor Program/Be The Match
National Ovarian Cancer Coalition
Patient Advocates In Research (PAIR)
Patient Empowerment Network
PD-L1 Amplifieds
Raymond Foundation
Sharsheret
The Clearity Foundation
The Exon 20 Group
The Life Raft Group
The White Ribbon Project
Triage Cancer
Upstage Lung Cancer