



July 22, 2022

Novitas Solutions, Inc.
2020 Technology Parkway
Suite 100
Mechanicsburg, PA 17050

Re: Public Comments for Proposed Local Coverage Determination, "Genetic Testing for Oncology (DL39365)"

Submitted electronically to ProposedLCDComments@novitas-solutions.com

Dear Medical Affairs:

On behalf of LUNGevity Foundation, the nation's preeminent lung cancer nonprofit that funds research, provides education and support, and builds communities for the approximately 236,000 Americans diagnosed with lung cancer each year¹ and the 541,000 Americans living with the disease,² we appreciate the opportunity to provide comments on the proposed local coverage determination (LCD) on Genetic Testing for Oncology (DL39365).

LUNGevity is a leading patient advocacy organization that represents the voice and interests of the national lung cancer survivor community by accelerating patient-centered research, empowering patients to be active participants in their treatment and care decisions and identifying and helping to remove access barriers to high quality care. As such, LUNGevity supports efforts to improve coverage and reimbursement policies so that access to comprehensive biomarker testing is increased. However, we are concerned that language in DL39365 that is unclear and confusing will impede patient access to biomarker testing. The principal area that requires clarification is how DL39365 relates to the existing Novitas LCD [L35396](#), Biomarkers for Oncology, which includes coverage recommendations for small gene panels for lung cancer patients. If the goal is to use the new proposed LCD to expand coverage to include broad molecular panels (comprehensive biomarker testing), we recommend elucidating several areas of DL39365 per the recommendations in this letter. However, if Novitas intends for the proposed LCD to replace L35396, we recommend rescinding DL39365 and developing a new proposed LCD that articulates coverage for comprehensive biomarker testing, including broad RNA and DNA-based molecular panels, in concordance with National Comprehensive Cancer Guidelines.³

Timely access to diagnostics that inform treatment decisions is critical for all patients, especially those with cancer. Biomarker testing, typically through comprehensive genomic profiling (such as Next-Gen Sequencing panels) and testing for protein markers (such as PD-L1 for immunotherapy), is the first step to accessing precision medicine, which can lead to improved outcomes.



Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, making up 85% of lung cancer cases.^{4,5} The complex nature of this disease requires personalized management plans for patients.⁴ Since the discovery of the first epidermal growth factor receptor (EGFR) mutation in lung cancer in 2004,^{6,7} targeted therapies have become a major component of the treatment arsenal for NSCLC patients.^{4,5} Currently, 8 driver mutations in lung adenocarcinoma have matched targeted therapy options (ALK fusions, BRAF V600E, EGFR including Exon 20 insertions, KRAS G12C, MET Exon 14 skipping mutations, NTRK fusions, RET fusions, ROS1 fusions) with several more such as HER2 with impending FDA approval.⁴ Indeed, lung cancer is now leading the field of precision medicine where research is rapidly progressing to develop better targeted therapies.

Recommended changes to the proposed LCD:

We recommend the changes below to ensure that the proposed LCD explicitly articulates coverage for broad molecular panels as recommended in NCCN medical guidelines.³

Use consistent, accepted language on testing terminology.

The proposed LCD uses the terms “biomarker testing” and “genetic testing” to refer to testing for molecular alterations to guide oncologic treatment. However, the mainstream vernacular use of “genetic testing” typically refers to germline testing for inherited mutations and cancer risk. Use of “genetic testing” could unintentionally lead to payer, provider, or patient confusion when interpreting the proposed LCD, possibly resulting in access barriers. Recent consensus recommendations for testing terms in precision medicine urge healthcare stakeholders to use “biomarker testing” when referring to testing for somatic alterations and other non-genomic biomarkers such as PD-L1 and MSI.⁸ Please replace “genetic testing” with “biomarker testing” to be consistent throughout the LCD, ensure ease of interpretation of the proposed LCD, and align with standard recommended terminology.

Clarify the intent to cover broad NGS panels, including laboratory-developed and FDA-approved tests, in concordance with medical guidelines.

The language in DL39365 does not specifically articulate coverage for broad molecular panels, yet comprehensive biomarker testing – which includes laboratory-developed NGS panels that demonstrate analytical/clinical validity and FDA-approved NGS tests – are standard of care for many patients with advanced stage non-small cell lung cancer across the continuum of care. An NGS panel at the time of diagnosis (primary cancer before first-line treatment is initiated) and/or subsequent NGS panels at recurrence/progression (given that tumors evolve with time)⁹ simultaneously checks for multiple clinically actionable mutations that help guide physicians to targeted therapies to treat NSCLC.³ This, in turn, enables timely matching of the patient to the right targeted therapy should a targetable mutation be present. NCCN guidelines recommend multiplex testing such as NGS platforms for making treatment decisions.³ Other



MACs such as Palmetto GBA, Noridian, Wisconsin Physicians Service, and CGS have coverage standards for comprehensive genomic profiling.¹⁰⁻¹³ The coverage includes certain laboratory-developed NGS tests that meet clinical and analytical validity. Revisions to DL39365 that explicitly articulate coverage standards for broad molecular panels through next generation sequencing in concordance with NCCN guidelines and in alignment with other MACs would further guarantee patient access.

Provide explicit statements of coverage for broad NGS panels to help reduce barriers to biomarker testing.

Given Novitas' broad reach in states that have a high incidence of lung cancer, including many states with a high percentage of medically underserved patient populations, we are concerned that the proposed LCD could unintentionally exasperate access barriers to lung cancer care for those who are most at risk.¹⁴ Per recent data from the Flatiron Health database, the disparity in access to testing between Black/African American lung cancer patients and white patients is significant. Black/African American lung cancer patients are 10% less likely to undergo NGS testing to identify molecular alterations for treatment selection compared with those who are white.¹⁵ Providing explicit statements of coverage for broad NGS panels will help reduce barriers to biomarker testing, which is especially critical for medically underserved patients.

LUNGevity is grateful for the opportunity to comment on the above-captioned LCD and is eager to work with Novitas Solutions, Inc. to continue to ensure that patients have timely access to high-quality biomarker testing.

The recommendations outlined above can be discussed with me, my staff, and LUNGevity's Scientific Advisory Board, which is made up of some of the world's leading experts in lung cancer biology, practice management, access to innovative medicines, and overall patient care. I can be reached at 240-454-3100 or aeFerris@lungevity.org if you have any questions or would like to engage in further dialogue.

Thank you for your attention to this very important matter.

Sincerely,

A handwritten signature in dark ink, appearing to read "Andrea Stern Ferris", written in a cursive style.

Andrea Stern Ferris
President and Chief Executive Officer
LUNGevity Foundation



ABOUT LUNGEVITY:

LUNGEVITY's mission is to improve outcomes for people diagnosed with lung cancer. Our goals are three-fold: (1) to accelerate research to patients that is meaningful to them; (2) to empower patients to be active participants in their care and care decisions; and (3) to help remove barriers to access to high quality care. We have the largest lung cancer survivor network in the country and actively engage with them to identify, understand, and address unmet patient needs. We also have a world class Scientific Advisory Board that guides the programs and initiatives of the organization. Additionally, we collaborate with other lung cancer patient advocacy groups and organizations, such as the American Lung Association and CHEST, who serve the lung cancer community.

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