PERSONALIZED MEDICINE COALITION

September 8, 2023

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

Alicia Campbell, M.D.
Executive Contractor Medical Director
First Coast Service Options, Inc.
532 Riverside Avenue
Jacksonville, FL 32202

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

Dear Dr. Mann and Dr. Campbell:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions from across the health care spectrum, appreciates the opportunity to comment on the draft local coverage determinations (LCDs) titled "Genetic Testing for Oncology" recently issued by Novitas and First Coast Service Options (FCSO).[i] As drafted, we believe the LCDs will hinder providers' ability to effectively deliver personalized medicine to Medicare beneficiaries. PMC is concerned that the policies Novitas and FCSO would implement through these draft LCDs would limit patient access to critical genetic testing when it is clinically appropriate. Therefore, we urge you to address the issues identified in our comments before finalizing these policies.

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that cause disease. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error care of late-stage disease in favor of more streamlined strategies for disease prevention and treatment. PMC's members are leading the way in personalized medicine and recommend that patients who may benefit from this approach undergo appropriate testing and tailored treatment as soon as possible during their clinical experiences.

Based on the potential of personalized medicine to target treatments to those who will benefit, we believe this approach holds the greatest potential for improving patient outcomes and reducing overall health care costs without jeopardizing patient access to the health care interventions they need. Accordingly, we urge Novitas and FCSO to demonstrate increased support of personalized medicine as they move to implement coverage determinations that impact the field.

Statement of Neutrality

Many of PMC's members will present their own responses to the draft LCDs and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the draft LCDs titled "Genetic Testing for Oncology" (DL39365, DL 39367).

Reliance on "knowledge bases"

PMC appreciates Novitas and FCSO's attempts to develop coverage policies for genetic testing that can evolve with the science. We have significant concerns, however, with the process proposed in the LCDs to outsource evidentiary reviews to third-party "knowledge bases." The three "knowledge bases" identified in the LCDs — ClinGen, the National Comprehensive Cancer Network, and OncoKB — were not designed to serve as the basis for coverage determinations.

The Medicare Program Integrity Manual (PIM) outlines required evidentiary content that Medicare contractors,[ii] including Novitas and FCSO, must provide in every proposed and final LCD. This content includes evidence that supports coverage, limited coverage, maintenance of existing coverage (in cases of LCD reconsideration) or noncoverage. At a minimum, contractors are required to include:

- a complete description of the item or service under review;
- a narrative that describes the scientific evidence supporting the clinical indications for the item or service;
- the target Medicare population; and
- whether the item or service is intended for use by health care providers or beneficiaries.

The draft LCDs "Genetic Testing for Oncology" do not include elements of an evidentiary review established by Congress and the Centers for Medicare & Medicaid Services (CMS). The LCDs only include evaluations of how the proposed "knowledge bases" were analyzed and selected. We believe such evaluations are not sufficient replacements for a review of the scientific evidence considered in a coverage determination for a test and an explanation of the rationale for each contractor's decision.

The draft Novitas LCD contains a **"**Summary of Evidence for Specific Lab Tests," however, without clear criteria provided for each test's review all 13 tests were found not to meet reasonable and necessary criteria for Medicare patients. We believe that a more structured and transparent process for review that details level of evidence requirements for all tests considered within the draft LCD is warranted prior to the finalization of the coverage policy.

Presumptive non-coverage for tests

The LCDs' reliance on evidence in "knowledge bases" to determine coverage for oncology testing would create inappropriate barriers for providers and their patients in the midst of a cancer diagnosis and treatment.

It can take years for innovative tests to be included in consensus-based clinical practice guidelines, despite sufficient evidence of analytical and clinical validity and clinical utility for indications relevant to Medicare beneficiaries. Oncology biomarker tests such as multi-analyte assays with algorithmic

analyses (MAAAs), tumor mutational burden (TMB) tests, minimal residual disease (MRD) tests, and comprehensive genomic profiling (CGP) are not included in any of the three "knowledge bases" identified in the draft LCDs.

Historically, tests have been evaluated on a claim-by-claim basis if not covered by an LCD, rather than non-covered and subject to reconsideration as proposed in the draft LCDs. The draft LCDs include an option for entities to submit an LCD reconsideration request for a determination of whether a non-covered test meets CMS' "reasonable and necessary" criteria. As part of this reconsideration process, we understand that there would be a 60-day period during which a request is deemed valid and then the request can be placed on a waiting list for an undetermined period. Timely access to diagnostics is critical for all cancer patients and we worry that the presumptive non-coverage approach subject to reconsideration that is laid out in the LCDs may lead to delays in care.

Exclusion of ICD-10-CM Codes

Finally, PMC is concerned that the draft LCDs and their accompanying billing and coding articles will further impede patient access to genetic tests in individual clinical situations where ICD-10-CM "not otherwise specified" (NOS) codes are used by healthcare providers and where ICD-10-CM codes are associated with remission and monitoring of hematological malignancies.

Metastatic cancer patients are often in situations where the origin of their primary cancer remains unknown, or they have a recurrent cancer where the primary disease was resected. In such cases, location-specific coding is no longer applicable. Patients with advanced cancer are also often treated with systemic therapy that does not target a specific location of the body. Providers caring for such patients appropriately use ICD-10-CM NOS codes. ICD-10-CM NOS codes are generally excluded from the draft LCDs, rendering genetic testing services non-covered in this context.

Similarly, DNA testing is performed for hematologic malignancies to establish remission status. If the draft LCDs are finalized, the standard of care tests to establish remission for hematological malignancies will not be included for coverage. Additionally, the lack of remission-related ICD-10-CM codes in the draft will prevent genetic tests from being used to monitor conditions, as MRD testing, for example, is designed to do. MRD and other genetic tests impacted by this policy have been shown to be useful risk stratification tools to guide the choice of treatment at an initial diagnosis, to detect early relapse after treatment, or to assess risk of relapse after treatment.

Conclusion

Thank you for considering our comments. PMC welcomes the opportunity to serve as a resource for you in continuing to shape these coverage policies to improve beneficiary access to personalized medicine in oncology. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely yours,

Cynthia A. Bens
Senior Vice President, Public Policy

[i] Novitas Local Coverage Determination "Genetic Testing for Oncology" (DL39365). 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
First Coast Service Options Local Coverage Determination "Genetic Testing for Oncology" (DL 39367). 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

[ii] *Medicare Program Integrity Manual*. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf