AMERICAN CLINICAL LABORATORY ASSOCIATION

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*Sent Electronically via: ProposedLCDComments@novitas-solutions.com and ProposedLCDComments@fcso.com*

Dear Drs. Mann and Campbell,

On behalf of the American Clinical Laboratory Association (ACLA), I am pleased to submit written comments on the draft Local Coverage Determinations (LCD), DL39365 and DL39367, Genetic Testing for Oncology. ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care. ACLA appreciates our past dialogue on various policy topics and we look forward to working collaboratively with Novitas and First Coast Service Options (FCSO) to address issues in the draft LCD.

Based on the discussion during the August 2023 Open Meetings, it appears that one of the major drivers for the development of this draft LCD was highly-publicized instances of potential fraud involving billing for genetic testing.[1] ACLA and other stakeholders in the clinical laboratory space agree with the goal of preventing fraudulent testing. However, we are concerned that the many hurdles created in the draft LCD will impede patient access to appropriate genetic testing for oncology. ACLA believes that open, collaborative conversation between the MACs, clinical laboratories, and ordering providers can yield effective policy that addresses the MACs' concerns about fraud while ensuring patient access to appropriate testing is not disrupted. **ACLA requests a meeting with Novitas and FCSO to discuss the MACs' concerns regarding genetic testing for oncology and collaborate on a coverage policy that can address those concerns while ensuring current standards of care.**

**ACLA recommends the following, which are outlined in detail below:**

- To ensure access to clinically necessary testing and that the LCD complies with the Social Security Act,[2] we recommend that the LCD be modified to remove the limitation that tests not included in the three identified databases are presumptively non-covered. While Novitas and FCSO state that the Local Coverage Determination Reconsideration process can be used as an alternative pathway, this adds unnecessary lead time to the coverage of evidence- and guidelines-supported testing and is not a viable alternative coverage pathway.
- ACLA recommends that Documentation Requirements 2, 4, and 7 be removed.
- ACLA recommends that Novitas and FCSO insert language throughout the draft LCD to ensure that medically necessary reflex testing will be encouraged and supported. Additionally, ACLA

[1] OIG Reports: "CMS's Oversight of Medicare Payments for the Highest Paid Molecular Pathology Genetic Test Was Not Adequate To Reduce the Risk of up to $888 Million in Improper Payments" (A-09-22-03010), issued June 2023 and "Trends in Genetic Tests Provided Under Medicare Part B Indicate Areas of Possible Concern" (A-09-20-03027), issued December 2021.
[2] Section 1834A(g)(1)(A) of the Social Security Act

welcomes a conversation with Novitas and FCSO to provide an overview of the general flow of orders within the laboratory and to discuss how reflex test processes are developed and documented.

- ACLA recommends that the MACs design a transparent process for reviewing materials submitted by interested parties for coverage of a specific test. At minimum, this process should involve a response to the submitting stakeholder including the analysis of the MAC regarding the impact of the submitted material on a coverage consideration. We also recommend that the MACs not categorically exclude resources prepared by commercial entities.
- ACLA requests that additional ICD-10-CM codes be added to the Billing and Coding: Genetic Testing for Oncology Articles, A59125 and A59123, prior to the implementation of the policy. A full redline of suggested edits to the 79 ICD-10-CM Groups from the Coding and Billing Article can be found in the attached Appendix. While the codes in red text should be added to the local coverage article at a minimum, additions should not be limited to the provided list.

**1. Procedural Concerns and Lack of Pathway for Coverage if a Test is Not Included in One of Three Databases**

As ACLA noted in our response to the draft LCD in 2022, we have significant concerns about Novitas' reliance on third-party "knowledge bases" in lieu of independent evidentiary evaluations of individual tests.[3] ACLA does not believe that Novitas and FCSO have issued draft LCDs that meet the requirements for local coverage policies, 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 a coverage determination. But in the draft LCDs, Novitas and FCSO include only an evaluation of the knowledge bases whose sponsors presumably have considered evidence regarding genetic testing. The knowledge bases are not designed with coverage determinations in mind, and they are not subject to notice-and-comment or public review by stakeholders. This means that stakeholders have been deprived of an opportunity to contribute insights into the clinical value of specific tests. Notwithstanding the value of the information contained in the knowledge bases, they do not take the place of the required evidentiary review by Novitas and FCSO themselves.

Novitas and FCSO publicly stated that they "followed the precedent outlined in the CMS IOM Publication 100-02, Chapter 15, Section 50.4.5 - Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen," but we disagree that this is a comparable context. The Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen[4] relies on a compendia to expand coverage of drugs beyond the FDA label, while this LCD establishes non-coverage for all tests not included in the three databases. The compendia/third-party databases are being used for expressly different purposes and the Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen are not precedential in that regard.

We appreciate that Novitas and FCSO have indicated that beyond inclusion in the three knowledge bases, the option always exists for an LCD reconsideration request for a determination about whether a specific DNA/RNA test meets CMS IOM Publication 100-08, Chapter 13, Section 13.5.4 reasonable and necessary criteria. However, the reconsideration pathway lacks clarity and transparency. For instance, it is unclear what the timeline would be for the review and response to reconsideration requests and what, if any, opportunities will exist for the public to provide input on the decision for reconsideration. It is problematic that a test not included in one of the knowledge bases will be non-

[3] Available at: https://files.constantcontact.com/5b9f323f401/5f0fa705-4142-408c-b6ec-05814090857a.pdf.
[4] CMS IOM Publication 100-02, Chapter 15, Section 50.4.5 - Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen.

covered without any review of the evidence, until a reconsideration request is submitted and considered.

Currently, if a DNA/RNA test is not addressed in any current active LCD, coverage is determined on a claim-by-claim basis. While the current claim-by-claim coverage process does not guarantee coverage in the future, this abrupt change from claim-to-claim review to express non-coverage will have an immediate, negative impact on laboratories and beneficiary access.

**Recommendation: To ensure access to clinically necessary testing and that the LCD complies with the Social Security Act,[5] we recommend that the LCD be modified to remove the limitation that tests not included in the three identified databases are presumptively non-covered.**

**2. Concerns with Extensive Documentation Requirements**

As part of the Draft Billing and Coding Article, the LCD includes the following eight Documentation Requirements:

1. *All documentation must be maintained in the patient's medical record and made available to the contractor upon request.*
2. *Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.*
3. *The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code(s) must describe the service performed.*
4. *The medical record must demonstrate that the treating clinician who is responsible for the management of the patient's cancer or substantiated suspicion of cancer is the same person as the ordering clinician.*
5. *The medical record must include documentation to support an established diagnosis of cancer or a substantiated suspicion of cancer.*
6. *The medical record must include documentation of how the test results will directly impact the management of the patient's specific medical problem.*
7. *The medical record must clearly document the communication and discussion of pre-test and post-test counseling and the risk associated with genetic testing.*
8. *The medical record from the ordering clinician must clearly indicate all tests that are to be performed.*

While ACLA agrees that the inclusion of these items in the patient's medical record constitutes good medical practice and documentation, we are concerned that some of these requirements, specifically numbers 2, 4, and 7, go far beyond the documentation regulations in 42 CFR 410.32(d)(2-3). The clinical laboratory is responsible for performing the testing and submitting the claim to the MAC for processing. In most cases the laboratory does not have access to the full medical record of the patient, let alone are they able to confirm the presence of these specific requirements.

Throughout the LCD, there is confusion between the information expected to be held by the laboratory, which is submitting the claim, and the ordering provider, who holds the medical record and full documentation for the patient. While some labs are uniquely able to access the full medical record of the patients whose samples they process, such as academic medical centers, this is not representative

[5] Section 1834A(g)(1)(A) of the Social Security Act

of all clinical laboratories. Additionally, this draft LCD deals with complex testing, which is frequently referred out to either reference or specialized laboratories that are separate entities from that of the ordering physician. We believe that conversation between the MACs and a diverse range of laboratories to understand the workflow and medical information provided with a test order will greatly improve the draft LCD.

**<u>RECOMMENDATION:</u> ACLA recommends that Documentation Requirements 2, 4, and 7 be removed. We welcome a conversation between a diverse range of clinical laboratories and the MACs to discuss the goals of the original Documentation Requirements and, if needed, to collaboratively develop requirements that will meet the goals of the draft LCD while ensuring that patient access is not disrupted.**

### 3. Disruption of Laboratory Reflex Testing Ordering Procedures

The Overview of the draft LCD states the following:

> *If the ordering provider is not directly involved in management of a patient's cancer, their ordering of oncologic genetic testing is inappropriate. Tests not ordered by the physician who is treating the beneficiary's cancer are not reasonable and necessary.*

Beyond this overview, the definition of the "treating physician" and multiple items throughout the draft LCD and associated draft Coding and Billing Article reiterate that only the treating physician can order tests. We understand that the MACs likely intended for this to ensure that genetic tests for oncology are ordered only by a practitioner who is knowledgeable about their use and the information they yield. However, we are concerned that this strict requirement will negatively impact medically necessary reflex testing. In reflex testing, an ordering provider and the laboratory will have a pre-set order of tests that are performed, following the results of the first test(s). Even though the ordering provider has agreed to this reflex pathway ahead of time, the pathologist will be the individual "ordering" the agreed upon follow-up tests.

Some examples of reflex testing pathways that are supported by the NCCN guidelines include:

- Non-Small Cell Lung Cancer (NSCLC)[6]: testing for *ALK* using fluorescence in situ hybridization (FISH) with a reflex to testing for *RET* and *ROS1* fusions.[7,8]
- Cutaneous Melanoma (stage III/IV)[9]: testing for *BRAF* and *KIT* with a reflex to broader genomic profiling.
- Colon Cancer[10]: testing for *KRAS*, *NRAS*, MSI, and MMR, then reflexing to a broader panel.

**<u>RECOMMENDATION:</u> ACLA recommends that Novitas and FCSO insert language throughout the draft LCD to ensure that medically necessary reflex testing will be encouraged and supported. Additionally, ACLA welcomes a conversation with Novitas and FCSO to provide an overview of the general flow of orders within the laboratory and to discuss how reflex tests processes are developed and documented.**

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[6] NCCN Guidelines Version 3.2023 - Non-Small Cell Lung Cancer (page 83 of 301)
[7] Gosney JR, Paz-Ares L, Janne P, et al. Pathologist-initiated reflex testing for biomarkers in non-small-cell lung cancer: expert consensus on the rationale and considerations for implementation. ESMO. 2023;8(4). https://doi.org/10.1016/j.esmoop.2023.101587
[8] Zacharias M, Absenger G, Kashofer K, et al. Reflex testing in non-small cell lung carcinoma using DNA- and RNA-based next-generation sequencing-a single-center experience. Transl Lung Cancer Res. 2021 Nov;10(11):4221-4234. doi: 10.21037/tlcr-21-570. PMID: 35004252; PMCID: PMC8674594.
[9] NCCN Guidelines Version 2.2023 Melanoma: Cutaneous (page 60 of 231)
[10] NCCN Guidelines Version 2.2023 Colon Cancer (page 27 and 28 of 223

### 4. Lack of Transparency with Review of Non-Covered Tests

Under the "Limitations," the draft LCD includes a list of thirteen specific tests that are considered "not medically reasonable and necessary." Based on the information that was included in the "Summary of Evidence," the contractors leaned heavily on PubMed and Google Scholar to search for "peer-reviewed, evidence-based literature that provided information regarding the analytic and clinical validity and clinical utility of these tests," on which the non-coverage determination was based. However, during the Open Meetings held on August 10 and 11, 2023, multiple stakeholders shared that they had submitted additional documentation and evidence to the MACs, which did not appear to be considered by the MACs prior to the non-coverage determination. In multiple instances, it was unclear if the MAC had reviewed the supplied information and decided against inclusion or if they did not receive it.

If the MACs will be determining non-coverage for specific tests within the LCD, especially for tests that currently receive approval on a case-by-case basis, we recommend that the data is reviewed in a transparent manner with multiple options for stakeholder input.

**RECOMMENDATION: ACLA recommends that the MACs design a transparent process for reviewing materials submitted by interested parties for coverage of a specific test. At minimum, this process should involve a response to the submitting stakeholder including the analysis of the MAC regarding the impact of the submitted material on a coverage consideration. We also recommend that the MACs not categorically exclude resources prepared by commercial entities.**

### 5. Restriction of Current Coverage for Numerous Diagnostic Codes

Novitas and FCSO state that "[t]he purpose of the LCD is not to limit beneficiary access to care but to ensure that Medicare is paying for services/tests that are deemed medically reasonable and necessary as supported by evidence." However, while Novitas and FCSO noted that the majority of the CPT codes non-covered in the Genetic Testing for Oncology article are not found in the current active LCDs, it does not appear that the changes in ICD-10-CM codes between current active LCDs and the final LCD have been compared. We have determined that the final LCD lacks many ICD-10-CM codes that are included in the current LCDs. Removal of these ICD-10-CM codes will impede access to standard of care and medically necessary testing for Medicare beneficiaries in the Novitas and FCSO jurisdictions, as detailed below.

> *"Not Otherwise Specified" (NOS) Codes:* In general, the draft LCD does not include NOS ICD-10-CM codes that currently have coverage under active LCDs. While more specific codes for standard and usual anatomic locations and gender can be used for cancer diagnosis, the NOS codes are the most appropriate diagnosis codes in some clinical cases. Frequently, the NOS codes are used for patients with metastatic cancer in which the origin of the primary cancer remains unknown or a recurrent disease where the primary disease was resected, as the location-specific coding is no longer applicable. Additionally, patients with advanced disease are often treated with systemic therapy that does not target a specific location of the body. ACLA is concerned that removal of the NOS codes from policy will prevent Medicare beneficiaries from receiving appropriate genetic testing for oncology because it is no longer clinically meaningful, and sometimes impossible, to have an ICD-10-CM code that specifies the laterality and location of a primary tumor.

Further, the use of NOS codes has been supported multiple times by the Centers for Medicare and Medicaid Services (CMS). In one instance, after discussion with stakeholders, CMS removed ICD-10-CM NOS codes from designation changes so as to not discourage their use during the FY 2022 IPPS Final Rule.[11] In another instance, CMS considered and then decided against removing the NOS ICD-10-CM codes from the National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2), as was indicated in a Transmittal 10832 from June 2, 2022 and later rescinded.[12]

Not only does exclusion of the NOS codes from the LCD go against current CMS guidance, but it also will create numerous discrepancies for claim submissions and confusion regarding coverage, as the NOS ICD-10-CM codes are associated with FDA-approved therapies.[13]

*Codes Associated with Remission and a Personal History of Cancer:* Another group of notable missing ICD-10-CM codes are those related to remission and a personal history of cancer. In many hematological malignancies, "remission" is determined following appropriate DNA testing. In these cases, the DNA testing is performed to establish remission status with the ICD-10-CM code updated to "remission" if it is consistent with the test results. As the policy is written, the standard of care tests to establish remission for hematological malignancies will not be included for coverage.

Additionally, 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), especially for MRD post-surgery in solid tumor cancers. In the Response to Comments, Novitas and FCSO state:

> *"[T]he limitation language is written in order to permit repeat testing that monitors a condition, such as MRD. In the case of testing that monitors a condition, each specimen is distinct by virtue of representing unique time points in the patient's clinical course."*

We appreciate Novitas' and FCSO's intent; however, the lack of remission-related and personal history of cancer ICD-10-CM codes will prevent tests from being used for this purpose. MRD and other genetic tests covered by this policy have been shown to be a useful risk stratification tool to guide the choice of treatment by providing information not only on the initial diagnosis, but also to monitor early detection of relapse after treatment or assess the risk of relapse after treatment.[14,15,16,17,18] This type of testing is considered standard of care and generally has been covered by Novitas and FCSO, even though it was not included in a specific LCD, and exclusion of these ICD-10-CM codes will result in decreased access to clinically indicated testing.

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[11] 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 Fed.Reg. 44774 (Aug. 13, 2021).
[12] Available at: https://www.cms.gov/files/document/r10832OTN.pdf.
[13] Available at: https://www.cms.gov/files/document/r12017otn.pdf.
[14] Hirsch P, Tang R, Abermil N, et al. Precision and prognostic value of clone-specific minimal residual disease in acute myeloid leukemia. Haematologica. 2017;102(7):1227-1237.
[15] Jongen-Lavrencic M, Grob T, Hanekamp D, et al. Molecular minimal residual disease in acute myeloid leukemia. N Engl J Med. 2018;378(13):1189-1199.
[16] Klco JM, Miller CA, Griffith M, et al. Association between mutation clearance after induction therapy and outcomes in acute myeloid leukemia. JAMA. 2015;314(8):811-822.
[17] Malmberg EB, Stahlman S, Rehammar A, et al. Patient-tailored analysis of minimal residual disease in acute myeloid leukemia using next-generation sequencing. Eur J Haematol. 2017;98(1):26-37.
[18] Morita K, Kantarjian HM, Wang F, et al. Clearance of somatic mutations at remission and the risk of relapse in acute myeloid leukemia. J Clin Oncol. 2018;36(18):1788-1797.

**Recommendation: ACLA requests that additional ICD-10-CM codes be added to the Billing and Coding: Genetic Testing for Oncology Article, A59125 and A59123, prior to the implementation of the policy. A full redline of suggested edits to the 79 ICD-10-CM Groups from the Coding and Billing Article can be found in the attached Appendix. While the codes in red text should be added to the local coverage article at a minimum, additions should not be limited to the provided list.**

Thank you for your consideration of ACLA's comments. We welcome the opportunity to work constructively with Novitas and FCSO to address the concerns and recommendations on the Genetic Testing for Oncology LCD.

Please contact Sarah Thibault-Sennett at sthibaultsennett@acla.com with any questions or to discuss further.

Best,

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