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RE: DL39367 and DL39365: Genetic Testing for Oncology

Dear Novitas and First Coast Options, Inc. Medical Directors,

The Advanced Medical Technology Association (AdvaMed) is pleased to submit the following comments to First Coast Service Options, Inc., and Novitas Solutions in response to the proposed Local Coverage Determination (LCD): Genetic Testing for Oncology (DL39367 and DL39365) and accompanying billing and coding articles (DA58918 and DA58917).

AdvaMed's member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

We thank First Coast and Novitas in advance for reviewing our recommendations to this LCD. LCDs provide beneficiary access to life-saving and medically necessary products and procedures. When followed, the local coverage process results in coverage decisions on items and services that benefit Medicare beneficiaries through an open and participative decision-making process. However, upon review of these draft LCDs, we have significant concerns that the current procedural requirements were not properly followed. As a result, if finalized, these draft LCDs would result in a significant narrowing of coverage that is currently available to Medicare beneficiaries with cancer.

Due to the significant nature of these concerns, described in more detail below, we urge Novitas and First Coast to withdraw DL39367 and DL39365 and not finalize at this time. Instead, we recommend that Novitas and First Coast convene stakeholders and the Carrier Advisory Committee (CAC) to receive input prior to development of a new policy. Incorporation of these recommendations is a step in right direction to ensure clarity and alliance with current medical practice, as well as provide a clear path forward and

continued coverage for tests currently covered under existing coverage policies (e.g., Novitas Biomarkers for Oncology LCD (L35396)).

I. The draft LCDs conflict with regulatory and statutory procedural requirements for evidence supporting LCDs

AdvaMed is very concerned that the draft LCDs were developed without properly following evidence requirements outlined within Chapter 13 of the Program Integrity Manual (PIM)[1] and the 21st Century Cures Act[2].

The draft LCDs fail to include the second requirement below, as stated in the PIM §13.5.3:

> *In every proposed and final LCD, the MAC must summarize the evidence that supports coverage, limited coverage, maintenance of existing coverage in cases of LCD reconsideration or noncoverage. At a minimum, the summary should include the following:*
>
> - *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.*

Similarly, the 21st Century Cures Act (the Act) mandated specific procedural requirements that Medicare Administrative Contractors (MACs) must follow. Specifically, the Act states:

> *"The Secretary shall require each Medicare Administrative Contractor that develops a local coverage determination to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination*
>
> *(i) Such determination in its entirety*
> *(ii) Where and when the proposed determination was first made public.*

[1] Medicare Program Integrity Manual, Chapter 13 Local Coverage Determinations https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf
[2] 21st Century Cures Act, H.R. 34, 114th Congress. (2016). https://www.congress.gov/bill/114th-congress/house-bill/34/text

(iii) *Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.*

(iv) *A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.*

(v) *An explanation of the rationale that supports such determination."*

When drafting these LCDs, Novitas and First Coast did not provide a summary of evidence, only three databases provided by third party providers. This is inconsistent with the requirements stated above.

In addition to the use of external databases conflicting with both regulatory and statute procedural requirements, AdvaMed is concerned that the use of these databases leaves numerous questions as to how the contractors will utilize the information within the databases and incorporate it into a coverage policy. It is important to stress that these databases do not review all tests. ClinGen and OncoKB do not review multi-analyte tests and thus these tests, which are a significant portion of tests used in oncology, would be solely reliant on NCCN guidelines. Moreover, the LCD fails to include a rationale as to why other knowledge bases were not included, such as professional society guidelines.

II. The draft LCDs create coverage uncertainty and risk reduced access to Medicare beneficiary services.

LCDs must be easily digestible for providers to ensure that coverage policy is implemented properly. These draft LCDs and corresponding articles as written do not provide clarity as to what exactly will be covered moving forward. For example, the corresponding articles provide an explanation of how CPT code 81455 (targeted genomic sequence analysis panel; 51 or greater genes) should be billed by a provider, yet 81455 is not listed as a covered code within the Coding Information section of the Article.

Additionally, during the open meeting on June 24, 2022, Novitas announced that upon finalization of the draft coverage policies, three current LCDs will be retired, including the Biomarkers for Oncology LCD. Upon comparison of the draft LCDs with the existing policies that will be retired, our analysis shows that approximately 25 codes will be removed, yet no test-specific evidence was provided as to why coverage would be removed. Specifically, our members seek information on why coverage for multi-gene panels tests, provided under 81445 and 81450 and currently covered under the Biomarkers for Oncology LCD is not

included in the billing articles. This is once again inconsistent with the requirements contained within the PIM. Specifically, the PIM states "MACs shall explain the rationale that supports their coverage determination of covered, noncovered, or limited coverage. The rationale is the reasoning leading to the coverage determination."[1] Widespread confusion with interpreting these newly proposed LCDs by providers and other stakeholders has the potential to interrupt timely biomarker testing, delay care, and disrupt patient access to innovative targeted treatments.

We appreciate this opportunity to share our recommendations for your consideration. We reiterate our overarching recommendation that these LCDs not be finalized at this time, as this path forward is in the best interest of patients and will ensure continued and appropriate access to diagnostic services for cancer patients. Our members are committed to working with you. If you have any questions, please contact Tara Burke (tburke@advamed.org).

Sincerely,

Chandra N. Branham, J.D.

Senior Vice President and Head of Payment & Healthcare Delivery Policy