

April 6, 2022

Jonathan Blum

Principal Deputy Administrator and Chief Operating Officer

Centers for Medicare & Medicaid Services

7500 Security Boulevard

Baltimore, MD 21244

Delivered electronically

Dear Mr. Blum:

The undersigned organizations represent a diverse set of stakeholders interested in preserving access to critically important diagnostics for patients with advanced cancer and are concerned about the impact of the Center for Medicare and Medicaid Services (CMS) Transmittal 10832 from June 2, 2021, regarding the National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2). We understand that the agency intends to eliminate a range of ICD-10 “not otherwise specified” (NOS) codes effective on July 1, 2022. This change will non-cover genomic testing for a significant number of patients with advanced cancer and likely result in tens of thousands of inappropriately denied Medicare Part B and Part C claims. We respectfully request that you allow continued use of these ICD-10 NOS codes under NCD 90.2.

In 2018, the Center for Medicare and Medicaid Services (CMS) finalized NCD 90.2 and concluded that next generation sequencing (NGS)-based genetic testing is reasonable and necessary and covered nationally for patients with advanced cancer. Stakeholders applauded this coverage policy which has enabled better access to comprehensive genetic testing to inform cancer treatment selection. Cancer treatment increasingly involves the use of targeted therapies intended for specific populations of patients with certain somatic variants. NGS-based testing has become a valuable tool to ensure patients have access to the most appropriate therapy and patients’ lives are changed every day by having access to this essential information.

Specifically, the NCD states that these tests are covered if a patient has:

- either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer; and
- not been previously tested with the same test using NGS for the same cancer genetic content, and
- decided to seek further cancer treatment (e.g., therapeutic chemotherapy).

Many patients in these situations have metastatic cancer in which the origin of the primary cancer remains unknown, or a recurrent disease where the primary disease was resected, and location-specific coding is no longer applicable. Moreover, patients with advanced disease are often treated with systemic therapy that doesn’t target a specific location of the body. In other words, it is no longer clinically meaningful, and sometimes it is impossible, to specify the laterality and location of a primary tumor. For example, for a double-mastectomy patient with recurrent breast cancer, specifying if the cancer is in the right or left breast is no longer possible or relevant. In these situations, ICD-10 NOS codes are often used as other ICD-10 codes are inappropriate for the clinical situation.

We value CMS' efforts to ensure that the appropriate codes are being used for billing purposes. We also agree that it is important to ensure that coding allows for future research that ultimately informs patient care. We believe that CMS also understands our concern that NOS codes are needed for billing in certain cases and applaud the agency for listening to public comments during recent rulemaking in August 2021 and acknowledging that the "laterality affected might be difficult to determine in certain instances" involving neoplasms.¹ In this regulatory action as part of the FY 2022 IPPS Final Rule, CMS decided to leave out numerous cancer ICD-10 NOS codes from designation changes so as to not discourage their use in the in-patient setting. When Transmittal 10804 was originally released, CMS stated that provider education would occur, presumably to limit the use of these codes, however the FY 2022 IPPS Final Rule thwarted any provider education campaigns since the Final Rule is directly contrary to this policy decision.

Since CMS has now affirmed that these ICD-10 NOS codes remain valid and appropriate for other services for the same cancer patients, the decision to remove these codes for use specifically under the NGS NCD is confusing and contradictory. Codes that are appropriate to describe advanced cancers and are acceptable for Medicare services covered under Part A (including hospice), Part B, and Part D should remain acceptable under the NCD to enable coverage of laboratory testing for these same patients.

Protecting cancer patients' access to genetic testing that informs their treatment is critical. This policy decision will create unneeded complexities for cancer patients at a time when countless, serious decisions are required. Some of the consequences of removing these codes are:

Delays in Care

While labs often run test orders at risk of not being reimbursed to ensure patients have rapid access to needed genomic testing, in cases where labs resolve this coding issue prior to running the test, patients will face delays in care. Providers can't put their patients on targeted therapies without these test results and for patients with advanced cancer, there is no time to waste.

Confusion for Patients

Patients will receive an Explanation of Benefits (EOB) stating that their claim has been denied and they face out of pocket costs for what should be a covered, medically necessary service. This red tape will cause unnecessary anxiety and distress for patients whose service was appropriately coded for all Medicare services but molecular laboratory testing.

Frustration for Providers

Since NOS codes remain billable for other cancer care and laboratories are prohibited from assisting providers in selecting appropriate codes, providers may be unaware of the consequences for their patients. In many cases, the ordering physician will have to go back to the diagnosing physician for coding information, adding to their workload. These barriers could

¹ 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 FR 44774. August 13, 2021.

disincentivize providers from utilizing appropriate testing for their patients and are contrary to CMS's Patients over Paperwork initiative.

As highlighted above, if Transmittal 10804/10832 goes into effect many healthcare providers caring for patients with advanced cancer will be appropriately using ICD-10 NOS codes for those patients, but their cancer genetic test will no longer be covered under NCD 90.2, not because it isn't considered reasonable and necessary, but because of a coding technicality. Moreover, this decision does not align with the agency's noteworthy efforts to put Patients over Paperwork, end surprise billing, and improve transparency regarding healthcare costs and reimbursement. In keeping with the agency's goals to shield patients from unexpected bills, we urge CMS to retain these codes, thus ensuring that Medicare beneficiaries have access to NGS-based genetic testing without needing to navigate billing and coding red tape.

Thank you for your consideration of our request. Should you have any questions, please contact Jennifer Higgins at jhiggins@guardanhealth.com.

Sincerely,

AdvaMedDx

ALK Positive, Incorporated

American Association of Kidney Patients (AAKP)

American Clinical Laboratory Association

Association for Molecular Pathology

Bidesix

Brafbombers

Bristol Myers Squibb

Cholangiocarcinoma Foundation

College of American Pathologists

Diaceutics, Inc.

Dusty Joy Foundation (LiveLung)

EGFR Resisters

Eurofins Clinical Diagnostics

EveryLife Foundation for Rare Diseases - Washington, DC

Exon 20 Group

Free ME from Lung Cancer

GO2 Foundation for Lung Cancer

Guardant Health

ICAN, International Cancer Advocacy Network

Illumina Inc.

KRAS Kickers

Laboratory Corporation of America Holdings

Life Raft Group

LungCAN

LUNGevity Foundation

Lung Cancer Research Foundation

Quest Diagnostics

Sonic Healthcare USA

Tempus Labs

The Biomarker Collaborative

The Coalition for 21st Century Medicine

Thermo Fisher Scientific

cc: Tamara Syrek Jensen, JD

Director, Coverage & Analysis Group