



May 5, 2022

Jonathan Blum
Principal Deputy Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Delivered electronically

RE: Removal of ICD-10 “Not Otherwise Specified” (NOS) Codes Under National Coverage Determination (NCD) 90.2

Dear Mr. Blum:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions across the health care spectrum, thanks the Centers for Medicare and Medicaid Services (CMS) for its efforts to implement coverage policies that support diagnostic innovations underpinning personalized medicine, such as next generation sequencing (NGS)-based genetic testing. By finalizing National Coverage Determination (NCD) 90.2ⁱ in 2018, CMS acknowledged that NGS-based genetic testing is reasonable and necessary and should be covered nationally for patients with advanced cancer.

In this context, I write now to share PMC’s concern over CMS’ subsequent transmittals,ⁱⁱ which we believe undermine the purpose of NCD 90.2 by removing more than 100 ICD-10 codes from use under NCD 90.2, including many “not otherwise specified” (NOS) codes. The removal of ICD-10 NOS codes could negatively impact patient access to NGS-based tests that are critical to informing cancer therapy selection and, therefore, should be reconsidered.

Statement of Neutrality

Many of PMC’s members will present their own responses to CMS 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 Transmittal 10804 and Transmittal 10832.

Importance of NGS-Based Genetic Testing to Personalized Medicine and Cancer Treatment

As you may know, personalized medicine is an evolving field that uses diagnostic tools to identify specific biological markers, often genetic, to help determine which medical treatments

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and procedures will be best for each patient. By combining this information with an individual's medical history, circumstances, and values, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans. Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error treatments of late-stage diseases in favor of more streamlined approaches to disease prevention and treatment, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction.

NGS has played an essential role in advancing our understanding of the altered genetic pathways involved in human cancers. As a result, cancer treatment increasingly involves the use of targeted therapies intended for specific populations of patients with certain genetic variants. NGS-based testing has become a valuable tool for delivering personalized medicine to patients by ensuring they have access to the most appropriate therapy.

Impact of ICD-10 Code Removal on Access to NGS-Based Genetic Testing

By issuing NCD 90.2 in 2018, CMS acknowledged that NGS is an important technology for patients with advanced cancer who may benefit from a specific treatment path. PMC was among the many stakeholders who applauded CMS' policy to cover NGS-based genetic testing for Medicare beneficiaries with recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer who decide to seek further cancer treatment. NCD 90.2 has enabled better access to comprehensive genetic testing to inform cancer treatment selection for these patients.

Metastatic cancer patients are often in situations where the origin of their primary cancer remains unknown, or they have a recurrent disease where the primary disease was resected. It is common for patients with advanced non-small cell lung cancer to have many tumors in both lungs making it difficult for a provider to say with certainty where the cancer began. Breast cancer patients who undergo double mastectomy are also in clinical scenarios post-surgery when location-specific coding is no longer applicable. Patients with advanced cancer are frequently treated with systemic therapy that does not target a specific location of the body. In these situations, ICD-10 NOS codes are used because other ICD-10 codes are inappropriate for the individual's clinical situation. In April of 2021, CMS issued Transmittal 10804, which proposed removal of more than 100 ICD-10 codes from use under NCD 90.2, including many NOS codes heavily used for advanced cancer patients. Transmittal 10804 was rescinded in May and replaced by Transmittal 10830 in June of 2021, which set the code removal date of July 1, 2022.

CMS also issued its FY 2022 IPPS Final Ruleⁱⁱⁱ on August 2, 2021, stating that advanced cancer is an acceptable and necessary use case for NOS codes. Under the FY 2022 IPPS Final Rule, ICD-10 NOS codes are acceptable for other Medicare-covered Part A, Part B, Part D, and hospice services for advanced cancer patients. It should stand to reason, then, that ICD-10 NOS codes are also acceptable for Medicare coverage of NGS-based genetic testing services for patients with advanced cancer, but as of July 1, 2022 they will be rejected.

Healthcare providers caring for patients with advanced cancer will be appropriately using ICD-10 NOS codes for those patients, but a patient's NGS-based genetic testing services will no longer be covered under NCD 90.2. In many cases, an ordering physician will have to go back to the patient's diagnosing physician for coding information, adding to their workload. These barriers could disincentivize some providers from utilizing appropriate testing for their patients. Furthermore, in cases where laboratories must resolve coding issues prior to running a test to ensure reimbursement, some advanced cancer patients will face delays in receiving results intended to guide their treatment.

PMC therefore urges CMS to continue allowing the use of ICD-10 NOS codes for coverage of NGS-based genetic testing under NCD 90.2. The removal of ICD-10 NOS codes as proposed will result in delays in care for some advanced cancer patients and non-coverage of NGS-based genetic testing for a significant number of patients with advanced cancer, which we know was not CMS' intent. Tens of thousands of inappropriately denied Medicare Part B and Part C claims can be anticipated if this change goes into effect.

Conclusion

Thank you for considering our comments. PMC welcomes the opportunity to serve as a resource for you as you strive to deliver appropriate, efficient, and accessible health care to patients. 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

cc: Tamara Syrek Jensen, JD
Director, Coverage & Analysis Group

ⁱ Centers for Medicare and Medicaid Services. *National Coverage Determination: Next Generation Sequencing (NGS)*. March 16, 2018. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCID=372&ncdver=1&bc=AAAAQAAAAAAAA>

ⁱⁱ Centers for Medicare and Medicaid Services. Transmittal 10804: *International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)*. May 17, 2021 <https://www.cms.gov/files/document/r10804OTN.pdf>

Centers for Medicare and Medicaid Services. Transmittal 10832: *International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)*. June 2, 2021. <https://www.cms.gov/files/document/r10832OTN.pdf>

ⁱⁱⁱ Centers for Medicare and Medicaid Services. *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*. August 2, 2022. <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipp-pps-final-rule-home-page>