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November 16, 2026

JoAnna Baldwin, M.S.
Acting Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Reconsideration of National Coverage Determination (NCD) 90.2 – Next Generation Sequencing for Medicare Beneficiaries with Cancer

Dear Ms. Baldwin:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 150 institutions from across the health care spectrum to promote the understanding and adoption of personalized medicine, thanks the Centers for Medicare & Medicaid Services (CMS) for accepting requests it has received to reconsider the National Coverage Determination (NCD) 90.2 – Next Generation Sequencing for Medicare Beneficiaries with Cancer.[i] PMC has engaged with CMS at multiple points since the initial coverage analysis of NGS was conducted in 2017 to ensure beneficiaries can access clinically appropriate testing.[ii] [iii] Since then, there have been significant advances in how NGS-based testing is utilized to inform care. Medicare beneficiaries make up more than half of the nearly 2 million cancer diagnoses in the United States each year.[iv] We are concerned that action on the requests to reconsider NCD 90.2 may be slowed by conflicting priorities. Such a delay could negatively impact the care many Medicare beneficiaries receive. PMC urges CMS to prioritize action to revise NCD 90.2.

PMC defines personalized medicine as an evolving field in which physicians use diagnostic tests and individual details about a person's health to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. 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 patient and provider experiences away from trial-and-error toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC and its members are leading the way in personalized medicine and in developing evidence showing how patients and the health care system can benefit from appropriate testing and tailored treatment as soon as possible during their clinical experiences.

Statement of Neutrality

Many of PMC's members will present their own responses to CMS on the reconsideration of NCD 90.2 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 adversely impact the ability of individual PMC members, alone or in combination, to pursue separate positions with respect to NCD 90.2 or coverage of NGS-based testing for Medicare beneficiaries.

Support for Expediting Reconsideration of NCD 90.2

Personalized medicines have now accounted for at least a quarter of new FDA drug approvals for each of the last 10 years.[v] Diagnostic testing plays a critical role in helping patients and providers evaluate their treatment options, allow for earlier disease detection, and in some cases reduce the cost and complexity of care. NGS has been essential to advancing our understanding of the altered genetic pathways involved in human cancer. PMC appreciates CMS' consistent recognition that NGS is an important technology for identifying cancer patients who may benefit from a specific treatment path. A decade of growth in personalized medicine and improvements in cancer care support updating NCD 90.2. We urge CMS to expedite reconsideration of NCD 90.2 to align with advances in clinical evidence

Facilitating NGS-based testing for beneficiaries with earlier-stage cancers; ensuring NGS includes DNA or RNA sequencing

As a condition of national coverage for somatic testing, NCD 90.2 requires that a patient has "either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer." [vi] However, for certain cancers, the FDA-approved or cleared personalized medicine therapy indications are not limited to "recurrent, relapsed, refractory, metastatic, or advanced" cancer. Additionally, the clinical utility of NGS-based testing for patients with earlier-stage cancer is well-established. American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN) clinical guidelines support uses of NGS-based testing to assist in therapy selection and management of early-stage cancers including in non-small cell lung cancer, colon cancer, colorectal cancer, pancreatic adenocarcinomas, and gastrointestinal stromal tumors, among others.

The advanced cancer requirement under NCD 90.2 can make a beneficiary's access to an FDA-approved and Medicare-covered personalized medicine therapy dependent on a companion diagnostic (CDx) that is not covered. The same gap exists for RNA-based testing. FDA has approved NGS-based CDx tests that use RNA sequencing,[vii] yet NCD 90.2 leaves coverage of NGS tests using RNA sequencing to MAC discretion, even though somatic alterations may be identified through either DNA or RNA sequencing. Therefore, to facilitate treatment for earlier-stage cancers that aligns with FDA labeling and clinical guidelines, NCD 90.2 should be expanded to include coverage NGS-based testing for Medicare beneficiaries diagnosed with cancer, regardless of stage or whether the test uses DNA or RNA sequencing.

Allowing Coverage of NGS-based testing for minimal residual disease (MRD) and therapy monitoring

In addition to progress in the use of NGS-based testing as a CDx for cancer therapy selection, there now are several NGS-based tests both for minimal residual disease (MRD) and therapy response monitoring. By detecting changes in circulating tumor DNA, these tests can give patients and providers critical information to aid in the diagnosis of disease progression, recurrence or relapse. Importantly, these tests can identify patients eligible for targeted therapies. For example, the FDA has approved a MRD CDx for patients with muscle invasive bladder cancer.[viii] In another example, FDA recently approved a new drug for patients with advanced breast cancer whose cancer develops specific mutations during treatment,[ix] and patients eligible for this therapy are identified by an FDA-approved CDx through serial blood-based testing.[x] There are also guideline recommended use-cases for repeated NGS testing. For example, NCCN guidelines also recommend MRD

testing as part of treatment for adult acute lymphoblastic leukemia, multiple myeloma, bladder cancer, diffuse large b-cell lymphoma, and mantle cell lymphoma. These are all significant clinical developments transforming the management and care of cancer patients. Unfortunately, the current NCD creates a coverage gap for Medicare beneficiaries where NGS-based testing at multiple time points may be beneficial for their cancer treatment.

NCD 90.2 requires that a patient has "not been previously tested with the same test using NGS for the same cancer genetic content." This requirement has been interpreted to preclude national coverage of FDA-cleared or approved tests with monitoring indications.. Furthermore, because NCD 90.2 only covers a single NGS-based test per cancer diagnosis, it restricts access to serial testing with a CDx required by FDA-approved therapeutic labeling. Cancer disproportionately impacts Medicare beneficiaries, with the median age of a cancer diagnosis being 67 years of age.[xi] It is critical that they have access to tests that can improve their outcomes, particularly as the standard of care in personalized medicine for cancer evolves. The NCD should be revised to cover testing of a Medicare beneficiary at multiple timepoints when the testing is consistent with FDA labeling.

Expanding germline testing for hereditary cancers

Additionally, NCD 90.2 requires that a patient has "ovarian or breast cancer" as a condition of national coverage for germline testing. However, current guidelines support germline testing beyond these two cancer types. NCCN guidelines have supported germline genetic testing for all individuals with pancreatic cancer and many patients with prostate cancer.[xii] A provisional opinion from ASCO recommends germline testing for individuals with relevant family history of pancreatic cancer" as well.[xiii] Broad genetic testing is also recommended for prostate cancer patients – particularly those patients with metastatic disease, high-risk features, or relevant family history – and for all pancreatic cancer patients regardless of history.

The current NCD does not enable beneficiaries with hereditary cancers other than ovarian and breast cancer to access potentially life-saving germline testing. Given the expansion of clinical guidelines and growing evidence demonstrating that older patients with cancer may also carry genetic mutations linked to hereditary cancer syndromes,[xiv] CMS should revise its criterion to cover germline testing for beneficiaries beyond those with breast and ovarian cancer.

Conclusion

PMC appreciates CMS' efforts to foster innovation and ensure Medicare beneficiaries have access to breakthroughs that may improve their health outcomes. We believe recent evidence supports expedited reconsideration of NCD 90.2 and that delayed action can carry urgent consequences for beneficiaries whose testing is not covered under the NCD's current criteria. PMC looks forward to providing more detailed comments when the NCD is reopened. In the interim we look forward to working with you and other stakeholders in the community to ensure the Medicare program facilitates timely patient access to personalized medicine and technologies enabling this approach to care. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely,



Cynthia A. Bens
Senior Vice President, Public Policy

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