



November 6, 2020

Gabriel A Bien-Willner, MD, PhD, FCAP
Medical Director, MolDX
Chief Medical Officer
PalmettoGBA
Part B Policy
PO Box 100238 (JM)
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Columbia, SC 29202

Sent electronically

RE: Proposed Local Coverage Determination (LCD) MolDX: Minimal Residual Disease Testing for Cancer (DL38779)

Dear Dr. Bien-Willner:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions across the health care spectrum, appreciates the opportunity to comment on the *MolDX Proposed Local Coverage Determination (LCD) for Minimal Residual Disease (MRD) Testing for Cancer*.ⁱ Because of its importance in informing the delivery of personalized medicine, PMC supports the LCD process moving forward for MRD testing of hematologic malignancies and solid tumors in patients with a personal history of cancer. We are concerned, however, that the proposed LCD may unintentionally impact patient access to clinically relevant MRD testing now and in the future without further discussion on testing limits established by the Centers for Medicaid and Medicare Services' (CMS') *National Coverage Determination (NCD) on Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer* before issuing a final LCD.

Personalized medicine is an evolving field that uses diagnostic tools to identify specific biological markers, often genetic, to help determine which medical treatments 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 experience away from trial-and-error and 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's members are leading the way in personalized medicine and recommend that

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patients who may benefit from this approach undergo 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 on the proposed LCD 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 the MolDX proposed LCD for MRD testing for cancer or related issues.

Support for Coverage of MRD Testing and Considerations for Repeat Testing

As recognized in the proposed LCD, MRD testing can help determine critical aspects of care for patients with chronic lymphocytic leukemia, multiple myeloma, acute lymphoblastic leukemia, colorectal cancer, lung cancer, breast cancer, bladder cancer, esophageal cancer, and others. MRD testing is an increasingly important tool used by physicians to predict long-term patient outcomes, to gauge treatment response, to stratify patient risk and to assess signs of remission or relapse. To ensure that patients and providers can continue to receive these benefits, PMC highlighted issues related to NGS-based MRD testing in comments as CMS developed and refined its NCD on NGS for Medicare beneficiaries with cancer.

MRD testing is guideline-driven and, by definition, is an assessment that is performed more than once during a patient’s management. MRD assessment is a series of tests used for purposes beyond a patient’s primary diagnosis. PMC believed that CMS’ initial proposal limiting an NCD to a single test at the point of a patient’s diagnosis with advanced cancer was problematic because evidence was mounting that established the value of using NGS-based MRD tests that are conducted multiple times in the course of a patient’s care.

In our comments to CMS in 2018,ⁱⁱ we noted that by proposing to limit coverage for an NGS-based test in instances where a patient had “either not been previously tested using the same NGS test for the same primary diagnosis of cancer, or for repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician,ⁱⁱⁱ” the NCD would be too restrictive to support clinical testing services like MRD. We raised the single test limit issue again when the NCD was under revision in 2019.^{iv}

The language published in the final NCD was revised to state that coverage would be provided if a patient had “not been previously tested with the same test using

NGS for the same cancer genetic content.” This change is an improvement from the original NCD language, as it appears to be intended to block duplicative NGS testing while allowing repeated use of a test when there is an expectation for different cancer genetic content. We believe this revised language can be appropriately applied to NGS MRD testing to allow coverage of serial MRD tests.

We believe that the draft LCD presumes the NCD limits the ability of contractors to cover more than one MRD test in a patient with cancer, and therefore proposes an approach for MRD serial testing where the initial baseline test and subsequent assays together comprise a single test. While this policy allows multiple assessments (which we strongly agree must be covered to provide appropriate care for patients, per guidelines and clinical practice), PMC does not believe this definition of MRD testing is necessary given the new language of the revised NCD.

In light of the crucial benefits MRD testing provides for patients and providers, we urge further discussion with CMS and stakeholders on flexibility of testing limits under the NCD, before finalizing this LCD. In particular, we urge you to seek clarification from CMS with the goal that CMS will allow MoDx to use a much less complicated approach for coverage of MRD testing in the final LCD. The final LCD should convey a more rational framework for coverage of MRD testing. This will lead to simpler and more transparent coding and pricing for all stakeholders. We fear that not doing so will impede Medicare beneficiary access and lead to suboptimal care for some patients.

Conclusion

Thank you for your work on the proposed LCD and for considering our comments. PMC welcomes the opportunity to serve as a resource for you in continuing to shape this coverage policy that will impact patient access to personalized medicine. 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

ⁱ Palmetto GBA. *Proposed Local Coverage Determination (LCD): MOLDX: Minimal Residual Disease Testing for Cancer (DL38779)*. September 25, 2020. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=38778&ver=7&name=373*1|374*1|378*1|375*1|379*1|376*1|380*1|377*1|381*1&bc=AQAAAIAAA AAA

ⁱⁱ Personalized Medicine Coalition. *Comment Letter: Centers for Medicare & Medicaid Services — Proposed Medicare Coverage Decision Memorandum for Next Generation Sequencing for Medicare Beneficiaries with Advanced Cancer*. January 17, 2018. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_Comments_NGS_NCD.pdf

ⁱⁱⁱCenters for Medicare & Medicaid Services. *National Coverage Analysis (NCA) Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R)* <https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=296>

^{iv} Personalized Medicine Coalition. *Comment Letter: Centers for Medicare & Medicaid Services — Proposed Medicare Coverage Decision Memorandum for Next Generation Sequencing for Medicare Beneficiaries with Advanced Cancer*. May 29, 2019. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_CMS_NCD_NGS_Germline_Reconsideration.pdf

^v Centers for Medicare & Medicaid Services. *Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R)* <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=296>