



American Cancer Society
Cancer Action Network
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November 7, 2020

Harry Feliciano, M.D., MPH
Senior Medical Director
Palmetto GBA
17 Technology Circle
Columbia, SC 29203

Re: Proposed Local Coverage Determination (LCD): MOLDX: Minimal Residual Disease Testing for Cancer (DL38779)

Dear Dr. Feliciano:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to submit comments on the proposed local coverage determination (LCD) for minimal residual disease testing for cancer (proposed LCD). ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influences evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer.

ACS CAN supports the proposed LCD for minimal residual disease testing for cancer. The evidence base demonstrating the utility of diagnostic laboratory tests that analyze bodily fluids for circulating tumor DNA (ctDNA) biomarkers to detect minimal residual disease (MRD) has been growing and marks an important development in the diagnosis and treatment of cancer. Different testing techniques are used across both hematologic and solid cancers to assess and monitor MRD. These include flow cytometry, polymerase chain reaction, and next-generation sequencing (NGS) which encompasses a number of different sequencing techniques.

As indicated in clinical practice guidelines, such as the National Comprehensive Cancer Network's (NCCN) Clinical Practice Guidelines in Oncology, the application of ctDNA tests to detect MRD can be a reliable indicator of cancer recurrence or progression.^{1,2} Monitoring for MRD in patients offers an approach that can potentially indicate that cancer is returning before clinical or radiographical signals would detect such a recurrence. Additionally, MRD detection can indicate response to therapy and help direct patients to alternative or additional therapies for their cancer.³

¹ NCCN Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia (Version 2.2020).

https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed 11/4/2020.

² NCCN Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia (Version 3.2021).

https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed 11/4/2020.

³ Paiva, B., van Dongen, J. J., & Orfao, A. (2015). New criteria for response assessment: role of minimal residual disease in multiple myeloma. *Blood*, 125(20), 3059–3068. <https://doi.org/10.1182/blood-2014-11-568907>

While there have been coverage determinations in Medicare for ctDNA testing, they have primarily focused on non-small lung cancer and for treatment indications.⁴ ACS CAN is pleased that this LCD provides coverage for ctDNA testing for monitoring indications across cancer types. Furthermore, we appreciate this foundational policy will allow future tests to be included on an ongoing basis based on satisfactorily completed technical assessments under the Molecular Diagnostic Services (MOLDX) Program, to review and confirm a test's analytical and clinical validity.

The proposed LCD supports ACS CAN's view that coverage of biomarker testing should not be restricted to a single occurrence if the test is designed to monitor disease progression and therefore must be serially administered. Thank you for the opportunity to provide comments on this important issue for cancer patients. If you have any questions, please do not hesitate to contact Devon Adams at devon.adams@cancer.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Kirsten Sloan". The signature is fluid and cursive, with a prominent initial "K".

Kirsten Sloan
Managing Director, Public Policy
American Cancer Society Cancer Action Network

⁴ Douglas, M. P., Gray, S. W., & Phillips, K. A. (2020). Private Payer and Medicare Coverage for Circulating Tumor DNA Testing: A Historical Analysis of Coverage Policies From 2015 to 2019. *Journal of the National Comprehensive Cancer Network* : JNCCN, 18(7), 866–872. <https://doi.org/10.6004/jnccn.2020.7542>