



AMERICAN SOCIETY OF HEMATOLOGY

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June 18, 2019

Gabriel Bien-Willner, MD, PhD
Medical Director
MolDX at Palmetto GBA

RE: Proposed Local Coverage Determination (LCD): MOLDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (DL38047)

SUBMITTED ELECTRONICALLY VIA www.cms.gov

Dear Dr. Bien-Willner:

The American Society of Hematology (ASH) is pleased to offer comments on the proposed local coverage determination (LCD), Next-Generation Sequencing (NGS) Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies.

ASH represents over 17,000 clinicians and scientists worldwide, who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. The ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients in diverse settings including teaching and community hospitals, as well as private practice.

ASH was impressed with the comprehensiveness of the proposed LCD but has concerns related to the limitations on repeat testing under the section, *Situations in which Test should not be used or coverage is denied*. The proposed LCD states that the test in question will be non-covered if "another NGS test was performed for the same indication within the past 6 months." ASH urges reconsideration of this 6-month limitation to allow for more flexibility. Unfortunately, many hematologic malignancies progress very quickly and NGS tests may be needed more frequently than every 6 months for the same indication.¹

Thank you for the opportunity to provide comments on the proposed LCD, Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies. We welcome the opportunity to discuss these comments with you and your team. If you have any questions or require further clarification, please contact Leslie Brady, Policy and Practice Manager, at lbrady@hematology.org or 202-292-0264.

Sincerely,

Roy L. Silverstein, MD
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2019

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¹ Prebet T, et. al. Outcome of high-risk myelodysplastic syndrome after azacytidine treatment failure. *Journal of Clinical Oncology*. 2011 Aug 20;29(24):3322-7.