



AMERICAN SOCIETY OF HEMATOLOGY

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November 27, 2019

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Reconsideration of the National Coverage Determination on Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-0045OR)

Dear Ms. Jensen,

The American Society of Hematology (ASH) is pleased to provide comments on the Centers for Medicare & Medicaid Services' (CMS) Proposed Decision Memo on Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer.

ASH represents more than 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 sick cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia.

ASH appreciates CMS' engagement with stakeholders during the reconsideration process that resulted in the release of this Proposed Decision Memo. We thank the agency for reviewing the available evidence that supports the expansion of coverage for germline testing in the current National Coverage Determination (NCD). However, we are concerned that this policy as drafted would limit, rather than expand, Medicare beneficiary access to NGS-based testing for cancer. As such, we wish to provide the following comments.

In our letter to CMS dated May 29, 2019, we stated that we were concerned about two issues impacting patients with hematologic malignancies: the restrictions placed on repeat NGS-based testing and limiting the policy to NGS-based tests for advanced cancer without special reference to hematological malignancies. We continue to have concerns after reviewing the Proposed Decision Memo, albeit repeat germline testing is not applicable in this instance.

CMS currently covers an NGS-based test in patients with "recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer." CMS states in Section A of the Proposed Decision Memo currently open for comment that "the scope of this review is limited to next generation sequencing of germline mutations to identify patients with inherited cancer at any stage." Hematological malignancies are not staged in the manner outlined in the somatic testing section and therefore, may not meet the agency's definition of advanced cancer. NGS-based testing for somatic mutations is currently the standard of care in hematological malignancies and its use is likely to expand in the testing of germline mutations for these cancers as has been proposed in the referenced NCD memo. Without clarification, patients with leukemias, myelomas, and lymphomas may lose access to tests that are critical to accurate diagnosis. We respectfully request that CMS clarify that NGS-based tests for both

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somatic and germline mutations for hematological malignancies may be covered under the policy if it is reasonable and necessary and meets the other national or local coverage criteria.

Thank you for the opportunity to provide comments on this Proposed Decision Memo. We welcome the opportunity to discuss these comments with you and your team. If you have any questions or require further clarification, please contact Suzanne Leous, ASH's Chief Policy Officer, at sleous@hematology.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Roy L. Silverstein". The signature is fluid and cursive, with the first name "Roy" being the most prominent.

Roy L. Silverstein, MD
President