April 17, 2019

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Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Ms. Syrek Jensen,

The American Society of Hematology (ASH) and the Leukemia & Lymphoma Society (LLS) write to you today regarding the reopening of the National Coverage Determination for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N). ASH and LLS urge the Centers for Medicare and Medicaid Services (CMS) to consider NGS-based testing for non-advanced hematologic malignancies when reopening the NCD.

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.

LLS is the world’s largest voluntary health organization dedicated to fighting blood cancers. Our mission is to cure leukemia, lymphoma, Hodgkin’s disease and myeloma, and improve the quality of life of patients and their families. Over the past 70 years, LLS has invested over $1.3 billion in ground breaking research, funding nearly all of today’s most promising advances.

NGS-based testing is currently available to test for non-malignant or pre-malignant hematologic disorders and many of these tests are currently recognized as the standard of care for patients with hematologic malignancies, such as lymphoma, multiple myeloma, leukemia, myelodysplasia and myeloproliferative neoplasms. When compared to sequential single gene testing, NGS-based tests provide results more quickly, are less expensive, provide greater genetic coverage and yield more actionable results with less tissue. Furthermore, NGS can help differentiate often confused diagnoses, leading to better targeting of therapies for patients. For example, a subset of patients are mis-diagnosed with fibrotic myelodysplastic syndrome, when in fact they have primary myelofibrosis. For these reasons, ASH and LLS urge CMS to consider NGS-based testing for non-advanced hematologic malignancies when reopening the NCD.

ASH and LLS hope to have the opportunity to provide the most up-to-date evidence to demonstrate the clinical benefit of NGS testing for hematologic malignancies in support of coverage during the reconsideration process. Because new studies have been published since the issuance of CAG-00450N, it would be helpful for our Societies to see the evidence previously considered so that we can compare the data and justify our recommendation to change this policy.
For any questions or further clarification please contact Leslie Brady, ASH Policy and Practice Manager, at 202-292-0264 or lbrady@hematology.org or Bernadette O’Donoghue, Vice President, Office of Public Policy (LLS) at 202-969-1810 or bernadette.odonoghue@lls.org.

Sincerely,

Roy L. Silverstein, MD
President
American Society of Hematology

Gwen Nichols, MD
Executive Vice President/Chief Medical Officer
Leukemia & Lymphoma Society