January 17, 2018

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

RE: Proposed Decision Memorandum on Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG #00450N)

Dear Ms. Jensen,

The American Society of Hematology (ASH) is pleased to offer comments on the proposed decision memorandum on Next Generation Sequencing for Medicare Beneficiaries with Advanced Cancer. The proposal was issued in conjunction with the Food and Drug Administration (FDA)’s approval of the FoundationOne CDx (F1CDx). The test was viewed as part of FDA and the Center for Medicare & Medicaid Services’ (CMS) Parallel Review Program, where the FDA approval process and the CMS evaluation for coverage occur concurrently.

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 were pioneers in demonstrating the potential of treating various hematologic diseases through bone marrow transplantation, and continue to be innovators in the fields of gene and cellular therapy, regenerative medicine, and transfusion medicine. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians who provide care to patients in diverse settings including teaching and community hospitals, as well as private practice.

ASH commends CMS for recognizing the value of precision oncology diagnostics in the care of cancer patients and proposing to cover F1CDx. However, we have significant concerns about the broad scope of the policy and recommend that it be narrowed such that CMS provide coverage for F1CDx but remove the non-coverage portion of the policy. Removing the non-coverage portion of the policy will allow coverage determinations to continue to be made at the local level for other NGS-based hematology and oncology testing, including local decisions related to testing for blood cancers such as lymphoma, multiple myeloma, and leukemia. If this policy is finalized as currently drafted, it will disrupt care for the patients our members treat because none of the NGS-based tests currently recognized as the standard of care in this patient population would meet the coverage requirements in this proposed policy.

As drafted, the policy defines all current and future uses of NGS-based testing in oncology as not medically reasonable and necessary unless the test is FDA-approved or meets strict coverage with evidence development (CED) requirements. This draft is a non-coverage determination for many clinically valid and medically necessary testing services for extremely vulnerable patient populations, including those with hematological malignancies.
NGS-based testing has become a well-established part of delivering targeted therapies to the patients treated by ASH members. The coverage changes in this policy will disrupt the delivery of appropriate care, potentially resulting in negative health outcomes.

This proposal outlines a coverage policy for the following advanced cancers: lung, melanoma, breast, ovarian, and colon. CED would be available for NGS-based testing for all other advanced cancers, but this testing would not be covered for cancers that are not considered advanced. All currently used NGS-based tests for advanced leukemia and lymphoma would require CED, denying Medicare beneficiaries access to this testing until CED trials could be designed and implemented. This would be an unreasonable disruption in patient care that is currently delivered in accordance with established clinical guidelines such as those approved by the National Comprehensive Cancer Network and others.

ASH appreciates the agency’s proposal to provide national coverage for NGS-based testing for Medicare beneficiaries with advanced cancers; however, the draft policy as written does not reflect the complex reality of receiving FDA-approval or meeting the CED requirements. Both options may be cost-prohibitive for the majority of laboratories, including academic medical centers, performing clinically useful and valid tests. If an institution would like to pursue CED, they most likely will have to establish the appropriate infrastructure that is not already place.

As CMS considers changes to the scope of this policy, ASH would like to highlight the following language included in the proposal:

*Conditions other than oncology are outside the scope of this decision, therefore, we propose that only indications of cancer, other than those advanced cancers noted explicitly in our decision are non-covered.*

NGS-based testing is currently available to test for non-malignant or pre-malignant hematological disorders that must not be disrupted. Given ASH’s concerns about the scope and impact of this policy on NGS-based oncology testing, the Society wishes to remind CMS that any attempt to expand the scope of this policy beyond oncology contradicts the wording of the policy referenced above.

Furthermore, NGS is a technology, not a diagnostic test. By focusing this proposed policy on a specific technology without connecting it to a specific biomarker or Current Procedural Terminology (CPT) code, this policy runs counter to established practices to determine coverage which has evaluated clinical usefulness independent of test methodology. The proposal overrides established and carefully reviewed local coverage policies that provide coverage for the tests that help identify targeted therapies for our patients based on specific biomarkers and CPT codes. For example, National Government Services (a local Medicare carrier) provides coverage for gene panel testing in leukemia under code 81450 (5-50 genes, hematopoietic gene panels) in L36926: Genomic Sequence Analysis Panels in the Treatment of Acute Myelogenous Leukemia (AML). We anticipate that providers will revert back to using sequential single gene testing if this policy is finalized without significant changes because of their favorable coverage status. However, NGS-based tests provide results more quickly, are less expensive, provide greater genetic coverage and yield more actionable results with less tissue. ASH urges CMS to consider these factors when developing a National Coverage Determination that will not be revised regularly.

Thank you for this opportunity to provide comments on the proposed decision memorandum on NGS for Medicare beneficiaries with advanced cancer. ASH supports a final policy that covers the F1CDx, but we urge CMS to re-evaluate the non-coverage portion and allow coverage for NGS-based testing for cancer to continue to be made at the local level. This will ensure our patients retain access to the NGS-based testing shown to be clinically useful and referral to genetic counseling that guide treatment. We look forward to working with the
agency to improve this policy. If you have any questions or require further clarification, please contact Suzanne Leous, ASH Chief Policy Officer at sleous@hematology.org or 202-292-0258.

Sincerely,

Alexis Thompson, MD
President