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November 15, 2024

National Government Services, Inc.
P. O. Box 7108
Indianapolis, IN 46207-7108
www.ngsmedicare.com

Re: LCD DL37606 Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases

National Government Services, Inc.,

The American Society of Hematology appreciates the opportunity to review and share comments on the proposed LCD DL37606 *Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases.*

Many diseases in classical and malignant hematology are caused by germline or somatic mutations. Therefore, accurate diagnosis often relies on genetic testing results in patients in whom there is clinical suspicion for hematologic disease. The understanding of the genetic basis of hematologic malignancies has expanded in the past decade with the use of next-generation sequencing technology; next generation sequencing is a technique that uses massively parallel sequencing to identify variants or mutations across a wide range of genes[1]. The utility of next generation sequencing in the diagnosis, risk stratification, treatment, and monitoring of hematologic malignancies is evident by the incorporation of germline and somatic gene mutation testing in recommendations from national and international guideline committees, including the World Health Organization (WHO), The National Comprehensive Cancer Network (NCCN), the European LeukemiaNet (ELN, a not-for-profit alliance of 33 leading cancer centers devoted to patient care, research, and education), and the new International Consensus Classification (ICC) group, among others.

The Society appreciates and supports the National Government Services, Inc.'s efforts to support the coverage of genomic testing in hematologic conditions and encourages National Government Services to consider the importance and necessity of repeat testing for Myelodysplastic Syndromes (MDS). For example, mutational testing in MDS shows better risk stratification than the revised International Prognostic Scoring System for predicting the time to leukemia transformation[2,3]. However, since MDS clonally evolves over time[4], it is important to monitor the mutational profile over time to assess for impending leukemia transformation. In addition, mutational testing after stem cell transplantation has also proven useful to predict relapse[5]. Enforcing limitations on repeat testing may lead to limited access to critical health services for individuals with MDS, as repeat testing tracks changes in how a patient responds to their treatment and the status of their diagnosis. **Therefore, ASH recommends the removal of the following language from the proposed LCD:**

Repeat Genomic Sequential Analysis Panel testing is not reasonable and necessary in MDS after initial diagnosis and risk stratification.

ASH's Subcommittee on Precision Medicine has organized an initiative to summarize the existing evidence supporting the use and reimbursement of next generation sequencing testing and repeat testing, for patients suspected of harboring germline or somatic gene mutations that predispose them to hematologic malignancies or patients suspected of having a myeloid or lymphoid malignancy. For patients with a confirmed malignant diagnosis, the Subcommittee is currently assembling a comprehensive set of published studies that address the impact of next generation sequencing on patient diagnosis, management, risk stratification, and outcomes, and is also prioritizing studies showing the potential of next generation sequencing to reduce the time and cost of patient evaluation. The Society will distribute this summary with the Medical Directors as soon as it is published and available.

Thank you for your efforts in this area. Should you have any questions, please contact Carina Smith, ASH Manager for Health Care Access Policy at casmith@hematology.org.

Sincerely,

Mohandas Narla, DSc
President, 2024

Steven Allen, MD
Chair, Reimbursement Subcommittee
ASH Committee on Practice
New York State Hematology-Oncology Carrier Advisory Committee Representative

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