AMERICAN SOCIETY OF HEMATOLOGY
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January 5, 2024

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via http://www.regulations.gov

Re: Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Contract Year 2025 Medicare Advantage (MA) and Prescription Drug Benefit Program (Part D) proposed rule.

ASH represents more than 18,000 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 fields of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. Our mission is to foster high-quality, equitable care, transformative research, and innovative education to improve the lives of patients with blood and bone marrow disorders. With these goals in mind, we look forward to providing comments on the proposed MA and Part D policies of importance to ASH members and the patients we serve.

Annual Health Equity Analysis of Utilization Management Policies and Procedures

The proposed rule outlines updates to incorporate health equity considerations in the Utilization Management (UM) committee policies and procedures. The updates include requiring the UM committee to have a member with health equity expertise, having the UM committee conduct an analysis of the use of prior authorization on an annual basis, and making the analysis report available to the public. This proposed rule builds on the recently released CY 2024 Medicare Advantage and Prescription Drug Benefit Program final rule that requires all MA organizations using UM policies and procedures to establish a review committee to approve all UM policies and procedures. ASH commends CMS for establishing the UM committee in the final rule and supports the enhancements for transparency and health equity to the UM committee outlined in this proposed rule.

ASH has a longstanding commitment to improving health equity for individuals with hematologic diseases and disorders given the stark inequities in health care access, delivery, and outcomes among this patient population. For example, individuals with sickle cell disease (SCD) are impacted by several barriers, such as lack of access to health insurance, consistent coverage across all CMS programs, coverage for necessary specialty and wrap around services, as well as discrimination based on race and ethnicity. At the 64th ASH

Annual Meeting and Exposition, four studies (*Social Determinants of Health and Pulmonary Embolism Treatment and Mortality: The Nationwide Inpatient Sample*, *Evaluating the Impact of Lab-Based Eligibility Criteria by Race/Ethnicity in Frontline Clinical Trials for Diffuse Large B-Cell Lymphoma (DLBCL): A LEO Cohort Analysis*, *Analysis of 372 Adult Allograft Recipients Reveals Associations between Non-European Ancestry, Low Socioeconomic Status, and Receipt of HLA-Disparate Grafts*, and *An Analysis of the Worldwide Utilization of Hematopoietic Stem Cell Transplantation for Acute Myeloid Leukemia*) were presented demonstrating significant and persistent disparities in medical care and health outcomes among patients of different racial backgrounds, nationalities, and socioeconomic status across a range of blood disorders, underscoring the need to close gaps in the health care system and ensure care is delivered equitably. Meanwhile, the use of UM may disproportionately impact individuals who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. ASH therefore supports the integration of health equity considerations into the UM committee's assessments of UM policies and procedures.

ASH also supports the annual analysis of the use of prior authorization. While intended as a tool to assure that care is medically necessary, meets certain standards, and controls costs, prior authorization (PA) frequently creates barriers to patients accessing timely, medically necessary care. For example, as noted in the ASH Policy Statement Access to Hematology Care in an Age of Innovation, many individuals with SCD, for which recurrent severe acute painful crises and chronic daily pain are the most common complications, are forced to switch from long-acting pain medications they have been taking for years because of failed PA attempts or a new PA must be filed every month for the same medication, placing an unnecessary administrative burden on the physician. Therefore, ASH supports the provision that requires the UM committee to conduct an annual health equity analysis of the use of prior authorization. The Society also agrees with CMS' recommendation to make the analysis report publicly available in one centralized location to increase accessibility and transparency.

Biosimilar Biological Product Maintenance Changes and Timing of Substitutions

In this proposed rule, CMS will permit biosimilar biological products- that are normally not interchangeable- to be substituted for their reference products without requiring PA processes for enrollees currently taking the reference product. Reference product changes made during the contract year will be exempt from the PA process. The current policy, requiring approval for midyear formulary modifications involving biosimilar substitutions, poses a challenge for hematologists striving to provide the most effective and affordable treatments for their patients. It also places additional administrative burden on the physician to make this change for their patient. By allowing plans to treat biosimilar substitutions as "maintenance changes" that do not require prior authorization, enrollees will have expedited access to equally effective, but potentially more affordable, options sooner. Therefore, ASH supports this patient-centric change as it aligns with the Society's goals to improving health care access and affordability.

ASH is committed to combatting inequities and advancing patient-centered comprehensive care and we look forward to working with you to achieve these goals. Thank you for the opportunity to submit these comments and please contact ASH Manager for Health Care Access Policy, Carina Smith at casmith@hematology.org or 202-292-0264 should you have any questions.

Sincerely,

Mohandas Narla, DSc
President, 2024

Robert A. Brodsky, MD
President, 2023