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2023

President

Robert Brodsky, MD
Johns Hopkins University
Ross Building, Room 1025
720 Rutland Avenue
Baltimore, MD 21205
Phone 410-502-2546

President-Elect

Mohandas Naria, DSc
New York Blood Center
310 E 67th Street
New York, NY 10065
Phone 212-570-3056

Vice President

Belinda Avalos, MD
Atrium Health
215 N. Pine Street, Unit 4703
Charlotte, NC 28202
Phone 980-442-2000

Secretary

Cynthia Dunbar, MD
NHLBI/NIH
Translational Stem Cell Biology Branch
Building 10-CRC, Room 5E-3332
10 Center Drive
Bethesda, MD 20892
Phone 301-402-1363

Treasurer

Joseph Mikhael, MD, FRCPC, MEd
Translational Genomics Research Institute,
City of Hope Cancer Center
445 N. Fifth Street
Phoenix, AZ 85004
Phone 602-343-8445

Councillors

Christopher Flowers, MD, MS
Alison Loren, MD, MS
Bob Löwenberg, MD, PhD
Charlotte Niemeyer, MD
Sarah O'Brien, MD, MSc
Betty Pace, MD
Jamil Shammo, MD
Wendy Stock, MD, MA

Executive Director

Martha Liggett, Esq.

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: CY 2024 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS 1786-P)

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) Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System proposed rule for calendar year (CY) 2024.

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 field 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 following policies of importance to ASH members and the patients we serve.

Potential Separate Payment Under Inpatient Prospective Payment System (IPPS) and OPPS for Establishing and Maintaining Access to a Buffer Stock of Essential Medicines

ASH is pleased that CMS is considering the implementation of a separate payment under the IPPS to support the establishment and maintenance of buffer stock of essential medicines. We agree with the agency that a policy such as this one will help to mitigate shortages of essential medicines and safeguard and improve the care hospitals are able to provide to patients. Should CMS implement a policy in the inpatient setting, we encourage the agency to implement a similar policy to help patients who receive care in outpatient settings and physician practices. The ongoing problem of drug shortages in the United States is incredibly troubling for ASH members and our patients. Over the past several months, the shortages of methotrexate, cisplatin, carboplatin, and other drugs for hematologic disease have significantly impacted ASH members' practice and the patients they treat.

The incidence and duration of drug shortages is growing, and the shortages of critical hematology therapies lead to delays in and rationing of care, negatively affect treatment decisions, create emotional distress for patients and families, and result in worse health outcomes.

We owe it to patients to find solutions to this issue. While we appreciate that CMS seeks to incentivize policies that may limit shortages of essential medicines, we have concerns and recommendations that we hope CMS will take into consideration before this and any other policies are implemented in the inpatient, outpatient, and physician office settings.

Essential Medicines

In the proposed rule, CMS references the report titled *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* developed by the Office of the Assistant Secretary for Preparedness and Response (ASPR). This report prioritized 86 essential medicines as critical for minimum patient care in acute settings, or important for acute care of respiratory illnesses and conditions with no comparable alternative available. It is important to note that the only chemotherapeutic medication included on this list is cyclophosphamide, and the report does not include blood and blood products in its analysis and scope “due to differences in their supply chains.”¹

We recognize that this request for comment is specifically for application in the inpatient setting, and potential expansion to the hospital outpatient and physician office setting; however, we urge CMS to look beyond the list curated by ASPR and develop a broader definition of essential medicines that includes medications beyond those used in acute care. Specifically, CMS should ensure that the chemotherapy drugs that are currently in shortage and all blood and blood products be included.

ASH strongly recommends that CMS consider expanding the list of essential medicines used in establishing these potential additional payments to include other chemotherapeutics, such as etoposide, and other therapeutics such as a tyrosine kinase inhibitor and a Bruton’s tyrosine kinase inhibitor needed to treat different blood cancers. As mentioned, the current chemotherapy shortages are greatly impacting patients across the country. Examples of additional key drugs used in hematology to treat malignant diseases and classical (nonmalignant) conditions that are essential include rituximab for non-Hodgkin lymphoma (NHL) and general use, caplacizumab for thrombotic thrombocytopenic purpura (TTP), cyclosporine for aplastic anemia, warfarin for lupus anticoagulant syndrome and acute promyelocytic leukemia (APL) antibody syndrome, and ravulizumab for paroxysmal nocturnal hemoglobinuria (PNH). When these drugs are not available, it affects treatment decisions, creates unnecessary stress for patients and their families, and may cause challenging health outcomes for patients. If CMS were to support the establishment and maintenance of buffer stock of essential medicines, this will help to mitigate the effects of supply chain disruptions of this magnitude in the future. And while many hematologic diseases and disorders are rare, these drugs are often in short supply, yet lifesaving.

Additionally, ASH refers CMS to the Food and Drug Administration (FDA) Executive Order 13944 “List of Essential Medicines, Medical Countermeasures, and Critical Inputs,” which classifies blood

¹ Essential Medicines Supply Chain and Manufacturing Resilience Assessment, (May 2022), footnote 3, available at https://www.armi.usa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf

and blood products as essential medicines.² As highlighted in this Executive Order, blood and blood products are essential for addressing several medical conditions, particularly those in hematology, such as treatment for blood cancer or sickle cell disease. Moreover, the blood supply is a critical aspect of emergency preparedness, which we experienced during the COVID-19 pandemic when the pandemic had a significant impact on blood donations and collection efforts. Unfortunately, blood is not like other drugs and biologics in that it cannot be manufactured to meet demand. For these reasons, we urge CMS to include blood and blood products within the scope of the proposed payment policy for ensuring access to essential medicines.

Establishing and Maintaining a Buffer Stock of Essential Medicines

While ASH fully supports hospitals maintaining a buffer stock of essential medicines to mitigate future shortages, we believe that CMS should not implement this policy for any drugs in shortage until those shortages are resolved. We are particularly concerned that providing incentives to hospitals to establish and maintain buffer stocks right now may encourage drug hoarding and exacerbate existing drug shortages and supply chain challenges.

We are encouraged that CMS aims to incentivize hospitals to maintain a buffer stock of essential medicines. We also believe that CMS may consider incentives for hospitals to purchase essential medicines that meet high quality standards. For example, CMS could provide incentives that induce the purchase of higher quality drugs produced by more reliable manufacturers through a voluntary reporting system that would include financial rewards for purchasing drugs from manufacturers with more resilient supply chains. We believe that both incentivizing mechanisms would better enable hospitals to make informed decisions pertaining to the essential medicines and would lead to more efficient allocation of medical resources. This in turn could mitigate drug shortages and improve quality of care and patient outcomes.

ASH recognizes that maintaining a buffer stock is only one element of a resilient and reliable pharmaceutical supply chain. ASH supports this payment program as a step toward preparedness against shortages or emergencies. ASH simultaneously encourages CMS to explore complementary programs in alignment with the ASPR resilience report's solution strategies to improve the quality, diversity, and redundancies of the supply chain and strengthen its resilience and reliability.

Payment for Dental Services

To conform with the Medicare Physician Fee Schedule (MPFS) changes in policy to cover certain dental services when related to specific conditions, CMS has proposed an additional 229 dental procedure codes to clinical ambulatory payment classifications. ASH is pleased to see that CMS has proposed coverage and payment for dental services for chemotherapy, CAR T-Cell therapy, and the administration of high-dose bone-modifying agents (antiresorptive therapy), all when used in the treatment of cancer. ASH submitted [comments](#) on last year's MPFS proposed rule as well [comments](#) for this year's Request for Information from CMS related to dental recommendations for the CY2024 Review where we supported coverage of dental services for patients receiving CAR T-cell therapy,

² FDA Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs, (October 2020), available at <https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs>.

following bone marrow or hematopoietic stem cell transplantation, undergoing treatment for multiple myeloma receiving bisphosphonates and/or denosumab, receiving chemotherapy for blood cancer, for individuals living with sickle cell disease, and for individuals living with hemophilia. We thank the agency for this proposal and encourage you to finalize coverage for these necessary dental services.

Thank you again for the opportunity to submit these comments. We appreciate your continued efforts to protect patient access to medically necessary care. Should you require further information, please contact Suzanne Leous, ASH Chief Policy Officer at sleous@hematology.org.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Brodsky", with a stylized flourish at the end.

Robert A. Brodsky, MD
President