June 15, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1771-P
7500 Security Boulevard
Baltimore, MD 21244-1850

SUBMITTED ELECTRONICALLY at https://www.regulations.gov

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation (CMS-1771-P)

Dear Administrator Brooks-LaSure:

The American Society of Hematology (ASH) is pleased to offer comments on the fiscal year (FY) 2023 Hospital Inpatient Prospective Payment System (IPPS) proposed rule. We appreciate the opportunity to provide these comments to the Centers for Medicare and Medicaid Services (CMS) on the provisions impacting our members.

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 disease, 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.

Specifically, ASH is pleased to provide comments on the following provisions:

1. Proposed Changes to ICD-10-CM and ICD-10-PCS Coding Systems
2. Chimeric Antigen Receptor (CAR) T-cell MS-DRG
3. Improving Maternal Health Outcomes
4. Health Equity
5. Mechanisms to Address Rare Diseases and Conditions Represented by Low Volumes within the MS-DRG Structure
ASH thanks CMS and the ICD-10 Coordination and Maintenance Committee for the inclusion of the new diagnosis codes for von Willebrand disease (VWD) in the proposed rule. ASH worked with ICD-10 staff to develop and submit a proposal for new diagnosis codes for VWD at the March 2021 ICD-10 Coordination and Maintenance Committee Meeting. Previously, only one ICD-10 diagnosis code, D68.0, Von Willebrand disease, existed, for VWD and all subtypes. The proposal for the new codes was supported by new clinical practice guidelines for the diagnosis and treatment of VWD developed by ASH, in partnership with the International Society of Thrombosis and Haemostasis (ISTH), the National Hemophilia Foundation (NHF), and the World Federation of Hemophilia (WFH). The addition of the new VWD ICD-10 diagnosis codes will help with accurate documentation, diagnosis, and treatment of the different subtypes of VWD. Again, the Society thanks CMS and the ICD-10 Maintenance and Coordination Committee for their role in advancing and approving these new codes.

Chimeric Antigen Receptor (CAR) T-cell MS-DRG

ASH appreciates that CMS provided comments on MS-DRG 018, Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies and is supportive of CMS's continued review of CAR-T data and how the MS-DRG is working to ensure that this potentially life-altering therapy is reaching those in need. The Society understands that at this time the agency is not proposing any changes to the weight or to the procedure codes assigned to the MS-DRG and continues to support the methodology CMS uses to determine the relative weight for MS-DRG 018, which excludes clinical trials cases and cases with standardized pharmacy charges less than $373,000. These steps are critical to recognizing the high cost of caring for these patients.

It is difficult to predict what the costs associated with other future CAR-T therapies will be. There will likely be new or different side effects or additional agents that are co-administered with the therapy that may increase toxicity. The Society urges CMS to take these issues into account as the Agency continues to monitor and update MS-DRG 018 over time. ASH’s main priority is protecting and improving appropriate patient access to this potentially curative therapy.

Improving Maternal Health Outcomes

ASH supports the proposal to adopt the Severe Obstetric Complications electronic clinical quality measure (eCQM). The Society would like to highlight that this measure includes sickle cell disease (SCD) with crisis as a severe maternal morbidity diagnosis which would be captured by this measure as a severe obstetric complication if a SCD crisis were to occur during the hospitalization for delivery.

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We applaud CMS’s recognition of SCD as a severe obstetric complication because women with SCD are especially at high risk of pregnancy related complications, including death; complications of SCD include severe alloimmunization, strokes, heart failure, or kidney failure. Barriers to receiving high quality, comprehensive care for SCD are a significant problem in the United States, resulting in health care disparities and inequities. This is especially true for women with SCD who are pregnant: they are ten times more likely to die in childbirth than non-Hispanic Black women without SCD. This disparity is compounded by the fact that the maternal mortality rate for all non-Hispanic Black women is already more than double the U.S. maternal mortality rate.\textsuperscript{3,4,5}

ASH believes it is essential to provide updated treatment guidelines that reflect the newest evidence about SCD, ensuring the medical community can better treat those with SCD and make the best decisions for their care. In 2019-2020, the following ASH Clinical Practice Guidelines on SCD were published in \textit{Blood Advances} and have recommendations that reference pregnancy: \textit{ASH 2020 guidelines for management of sickle cell disease: transfusion support}; \textit{ASH 2020 guidelines for management of sickle cell disease: acute and chronic pain}; and \textit{ASH 2019 guidelines for management of sickle cell disease: cardiopulmonary and kidney disease}. These guidelines may be of use as CMS adopts the Severe Obstetric Complications eCQM.

**Health Equity Measures**

ASH is strongly supportive of CMS’ efforts to address health equity, including the inclusion of three new measures under the hospital inpatient quality reporting (IQR) program. ASH recognizes that persistent inequities in health care exist in the United States, and the Society has been a leader in combatting inequities in hematology, supporting scientists and clinicians from backgrounds underrepresented in medicine, and embracing diverse voices across the patient and health care communities. As such, the Society applauds CMS for including proposals in the IPPS proposed rule intended to improve health equity in CMS quality programs. ASH supports stratification of quality metrics based on social risk factors and race and ethnicity as an important step for giving hospitals, providers, and patients more comprehensive and actionable information on health disparities.

As the Agency’s health equity work progresses, ASH encourages CMS to give special consideration to rare disease populations which may be disproportionately impacted by health inequity. For example, SCD is an inherited blood disorder that affects an estimated 100,000 Americans, primarily African Americans and Latinos. Sickle cell trait (SCT) is even more prevalent and occurs in 1–3 million Americans and 8–10 percent of African Americans in the United States. When compared with other genetic conditions, such as cystic fibrosis, SCD has received relatively little attention and few resources from the scientific, clinical, and public health communities. In its report titled \textit{Addressing Sickle Cell Disease: A Strategic Plan and Blueprint for Action}, the National Academies of Sciences, Engineering, and

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Medicine identified the affected population being primarily composed of racial and ethnic minorities, which must contend with persistent discrimination in the health care system and racism in society at large, as a contributing factor to the lack of awareness and resources for SCD.6

ASH is working to improve SCD care, treatment, research, and data in the U.S. and in 2015 established a transformative, patient-centric, multifaceted Sickle Cell Disease Initiative to improve outcomes for individuals with the disease. As part of this work, ASH founded the ASH Research Collaborative (RC), which includes three SCD programs: a Sickle Cell Disease Clinical Trials Network (CTN); Data Hub program on SCD; and an SCD Learning Community. The Data Hub is a centralized real-world data program created to facilitate the sharing of data on hematologic conditions to support research and quality improvement. Using the Data Hub, the CTN can collect key information and identify gaps that will help advance SCD research and treatment options. There are currently 35 sites enrolled in the SCD Data Hub program, which represents 20,000 patients and once all sites who are part of the CTN are enrolled in the Data Hub there will be approximately 50,000 patients represented – nearly half of all people living with SCD in the U.S. In October 2020, the HHS Office of Minority Health awarded ASH with a grant to support the creation of a SCD clinical data platform (to enhance the SCD Data Hub), and a SCD Learning Community, which activates the implementation of evidence-based practice to improve sickle cell disease care and patient outcomes. ASH stands ready to work with CMS to enhance data collection and quality improvement efforts with the ultimate goal of improving health equity for individuals with SCD as well as with other hematologic diseases and disorders.

Mechanisms to Address Rare Diseases and Conditions Represented by Low Volumes within the MS-DRG Structure

ASH thanks CMS for the chance to provide comments on how to address critical access issues related to rare diseases and conditions that are represented by low volumes in CMS claims data. Evolving science and research have allowed for the discovery of new and promising, but many times, high-cost therapies that must be provided as part of inpatient hospital care. In many circumstances, these high-cost therapies are for rare hematologic diseases, with few or no other treatment options. It is difficult under the existing MS-DRG system for hospitals to be adequately reimbursed for high-cost, innovative therapies, and this problem is exasperated if the therapy is for a rare disorder.

Two of the three examples provided in the proposed rule are hematology-related. First, CMS highlighted treatment access issues for individuals with porphyria, a rare metabolic disorder caused by a genetic defect within the heme biosynthetic pathway. Specifically, CMS discussed three prior requests to review the MS-DRG classification for cases of patients diagnosed with porphyria. The Agency also highlighted comments received related to access to Panhematin, used to treat patients having an acute porphyria attack. Secondly, CMS outlined access issues in the inpatient setting for the administration of Andexxa, used to reverse the anticoagulant effects of two direct oral anticoagulants. In both cases, CMS data showed that the average costs for these specific cases were higher when compared to the other cases in their respective MS-DRGs, but ultimately, CMS was unable to identify another MS-DRG that would be more appropriate.

Again, ASH appreciates that CMS is addressing this issue and suggests several concepts as potential solutions for discussion:

1. Create a rare disease modifier, similar to the complication or comorbidity (CC) and major complication or comorbidity (MCC) modifiers, which could be used to distinguish MS-DRGs with high-cost treatments for rare disorders.

2. Create a rare disease MS-DRG, specifically for rare hematologic diseases and disorders. As mentioned earlier, many rare hematologic diseases and disorders have effective but high-cost therapies, and more are expected in the coming years, such as gene therapy for sickle cell disease, which will be administered in the inpatient setting. Because it would be specific to hematology, the base services and care would likely be similar across the different diseases and disorders.

3. Implement long-term add-on payments for high-cost drugs with Orphan Drug status, similar to New Technology Add-on Payments.

4. For rare or ultra-rare conditions, waive the 500-inpatient-stay volume threshold for a MS-DRG change request.

Because rare diseases and disorders and high-cost therapies are so prevalent in hematology, ASH encourages CMS to address this issue not only broadly but also specifically for hematology. The Society would be happy to work with the Agency on this process, including to help identify other rare hematologic diseases and disorders for which this is a problem.

In closing, the Society thanks CMS for the opportunity to provide input on the proposed 2023 Medicare IPPS rule. Please reach out to ASH Chief Policy Officer, Suzanne Leous (sleous@hematology.org), with any questions or clarifications regarding our comments.

Sincerely,

Jane N. Winter, MD
President