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September 9, 2024

Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1784-P
P.O. Box 8016
Baltimore, MD 21244-8016

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

RE: CY 2025 Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (CMS-1809-P)

Dear Administrator Brooks-LaSure:

The American Society of Hematology (ASH) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Medicare CY 2025 Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) Payment System Physician

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 provide comments on the following policies of importance to ASH members who care for patients in private, community practices, hospital practices, and academic settings.

Payment for Cell and Gene Therapies

For CY 2025 only, CMS proposed **not to package payment** for the cell and gene therapies products when those therapies appear on the same claim as a primary comprehensive ambulatory payment classification (C-APC). Generally, CMS provides a single payment for all the services and therapies that are included in a comprehensive ambulatory payment classification (C-APC). In this case, CMS proposes to pay for the cell or gene therapy separately using the average sales price methodology.

C-APC payments are designed to cover all the services provided during a hospital outpatient visit that are integral, ancillary, supportive, dependent, or adjunctive to the primary service, which would include cell and gene therapies. However, CMS states that these therapies **are** the primary treatment being administered to a patient and thus, are not integral, ancillary, supportive, dependent, or adjunctive to any primary C-APC services. The cell and gene therapies do not "support" another procedure.

The Society supports this policy as proposed. Given the high cost of cell and gene therapies, payment for the therapy outside of the C-APC bundle will promote the availability of innovative and life-saving treatments to Medicare beneficiaries. If payment were included in the C-APC, there would be few if any, Hospital Outpatient Departments (HOPD) that could support providing this care. We thank CMS for continuing to recognize the value of cell and gene therapy. Additionally, CMS seeks comment on a variety of topics to enable the Agency to make informed decisions on future policies related payment for cell and gene therapies. The following is a list of some of those questions, and ASH's response.

Are there other cell and gene therapies products not listed in Table 1, page 61 (display copy) of the rule that should be?
At this point, the list of therapies that CMS proposes to exclude from packaged payment is appropriate. As more therapies are developed and should the policy be extended, the list can similarly be expanded.

Should the proposal to pay for cell and gene therapies separately be extended beyond one year?
The Society does not think that the length of this proposed policy (one year) is long enough to collect the necessary data needed to inform how to most appropriately pay for these therapies in the HOPD setting. ASH recommends that CMS implement the payment policy for three years to allow for the collection of more robust data and to gain a better understanding of how well the policy is working.

Extending the policy for additional years is particularly important for cell and gene therapies generally because they are not provided in high volumes due to long cell manufacturing times and limited manufacturing facilities. Collecting sufficient data with which to make future policies will take time and we therefore recommend extending the payment policy for three years. Although the gene therapies for SCD are not included in TABLE 1: Cell and Gene Therapies Proposed for Exclusion from C-APC Packaging, these newly approved therapies are demonstrative of the challenges around how limited manufacturing for cell and gene therapy can impact the amount of data available to be collected. For example, for cell and gene therapy for sickle cell disease (SCD), there are only two companies that have FDA approval to manufacture gene therapies for SCD. The manufacturing capacity is very limited. One manufacturer can only produce gene therapy for approximately 100 individuals annually, meaning the volume of patients who may be able to receive this treatment is extremely low and therefore less data are available to meaningfully inform policy. By extending the policy for three years, CMS can gain a better understanding of how cell and gene therapies are delivered to Medicare beneficiaries in the HOPD.

Should CMS create a new C-APC, or similar packaged payment policy for the service of providing cell and gene therapies? If so, how should it be structured?
The Society believes that there is no accurate way to create a bundled payment for a whole group of cell and gene therapies. CMS should not create a new C-APC, nor should the payment for cell and gene therapies be captured in packaged payment policy. The costs of each cell or gene therapy are so disparate because each therapy has a different treatment protocol, from preparation requirements through administration and patient follow-up, that creating a singular packaged payment would not appropriately set up reimbursement to match the spectrum of included therapies and could lead to access to care issues.

What are the items and services that are "integral, ancillary, supportive, dependent, and adjunctive" to the provision of cell and gene therapies?
Given that care is quite different for each therapy, as previously noted, the agency will have to analyze claims for each cell and gene therapy, as noted in TABLE 1: Cell and Gene Therapies Proposed for Exclusion from C-APC Packaging in the proposed rule, to identify the items and services associated with each therapy. This will be important as to ensure that all the ancillary costs are captured appropriately for each therapy, including items that are specific to the individualized treatment plans for each cell and gene therapy.

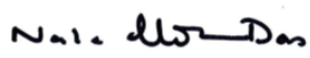
Payment for Services Associated with Administration of CAR T-cell Therapies
New Category I CPT® codes will replace the current Category III CPT® codes beginning on January 1, 2025. While not specifically discussed in the proposed rule, CMS's current policy does not include separate payment for services associated with CAR T-cell collection (3X018), preparation to transport the cells (3X019), and receipt of and preparation to administer the cells (3X020). The three CPT® codes that describe these services have been assigned a status indicator of "B," for CY 2025. The status indicator "B" indicates the codes are not paid separately under the OPPS. The CPT® code for cell administration (3X021) has a status indictor of "S" indicating separate payment under the OPPS.

The Society disagrees with current policy, and we recommend CMS provide separate payment for these services, which are separately identifiable, and unique steps in the CAR T-cell therapy treatment process. The Society encourages CMS to accept the recommendations of the Advisory Panel on Hospital Outpatient Payment, which met on August 26, 2024. The Panel voted to recommend to CMS that the status indictors for 3X018, 3X019, and 3X020 be changed from "S" to "B" which will indicate separate payment. Without separate payment for these steps in the CAR T-cell therapy process, it is likely that outpatient centers will not be able to continue providing CAR T-cell therapy services without reimbursement for all steps in the process. It is not clear how long this would be financially viable for institutions, and the lack of a separate payment for 3X018, 3X019, and 3X020 could create an access to care issue.

The services associated with each of these steps in the process are required for CAR T-cell therapy, and one service cannot be completed without the others. CMS has assumed that payment for these services can appropriately be captured and bundled into payment for the CAR T-cell therapy. This is not the case, as each of these steps requires distinct expertise and knowledge of the process. Additionally, the costs vary depending on the harvesting and preparation of the cells, the cell therapy being produced, and the preparation of those cells.

Thank you for the opportunity to provide comments on these issues. If the agency has questions or would like to meet to discuss our comments, please contact Carina Smith at casmith@hematology.org.

Sincerely,



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