American Society of Gene + Cell Therapy

August 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U. S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1809-P, Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities.

Dear Administrator Brooks-LaSure:

The American Society of Gene and Cell Therapy (ASGCT) appreciates the opportunity to comment on CMS-1809-P, a proposed rule that would update Medicare's Hospital Outpatient Prospective Payment System for 2025. ASGCT appreciates the proposal to exclude some gene and cell therapies from packaging in Comprehensive Ambulatory Payment Classifications (C-APCs) under the Outpatient Prospective Payment System (OPPS). The unique nature of gene and cell therapies merits novel approaches to payment under the OPPS and all of the Medicare payment systems overseen by the Centers for Medicare & Medicaid Services (CMS).

About ASGCT

The ASGCT is a nonprofit professional membership organization comprised of more than 6,400 scientists, physicians, patient advocates, and other professionals. Our members work in a wide range of settings including universities, hospitals, government agencies, foundations, and biotechnology and pharmaceutical companies. Many of our members have spent their careers in this field performing the underlying research that has led to today's robust pipeline of transformative therapies.

A core portion of ASGCT's mission is to advance the discovery and clinical application of genetic and cellular therapies to alleviate human disease. To that end, ASGCT supports Medicare payment policies that foster the adoption of, and patient access to, new therapies, which thereby encourage continued development of these innovative treatments. The Society's support

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of sufficient and appropriate reimbursement levels to providers to facilitate patient access does not imply endorsement of any individual pricing decisions.

2025 Proposals

CMS proposes to exclude qualifying cell and gene therapies from C-APC packaging for 2025. CMS also seeks comment on:

- *Whether there are any additional cell and gene therapies that may be appropriate to exclude from C-APC packaging for CY 2025.*
- *Whether to extend this policy beyond year 1, or if a different supplemental policy approach may be warranted in future rulemaking.*
- *Whether there are other classes of drugs, biologicals, or other products that are not clearly integral, ancillary, adjunctive, or supportive of a primary C-APC service.*

ASGCT supports CMS' proposal to exclude cell and gene therapies from C-APC packaging methodology. Under the C-APC methodology, CMS' intent has historically been "to make a single prospective payment based on the cost of all individually reported codes that appear on a claim with the primary C-APC service," which CMS believes to "represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service." (Quotations from CMS' proposed rule).

In the proposed rule, CMS notes that gene and cell therapies are generally not ancillary to the primary service involved in their administration. ASGCT agrees, as the therapies are typically the core intervention involved in any procedure in which they are associated. Recognizing the unique nature of gene and cell therapies, CMS has proposed not to package payment for a specified set of cell and gene therapies "that function as primary treatments and do not support C-APC primary services."

ASGCT encourages CMS to finalize the proposal. Furthermore, ASGCT encourages CMS to extend the policy indefinitely. Historically, policies that package the cost of gene and cell therapies into single lump sum payments to providers run the risk of unfairly penalizing providers who offer the services by issuing payments that undervalue the cost of acquiring the therapy. While CMS has taken steps to mitigate these impacts, particularly in the inpatient setting (use of the New Technology Add-On payment, creating a separate Diagnosis Related Group (DRG)), the nature of gene and cell therapies continues to create stresses on the payment system. Separate payment for gene and cell therapies is a critical methodological step to ensuring no provider will face a financial penalty for agreeing to offer these innovative and life-changing products to Medicare patients.

CMS seeks comment on whether to make other changes to the C-APC packaging policy in future years. Specifically, CMS seeks comment on the following questions:

> *(1) Because the cell and gene therapies listed in Table 1 are not integral, ancillary, supportive, dependent, or adjunctive to any current C-APC procedure, how could CMS structure a new C-APC, or similar packaged payment policy, for the service to administer cell or gene therapies, such by creating as a Chimeric Antigen Receptor (CAR) T-cell therapy administration C-APC, with which the CAR-T or gene therapy would be integral, ancillary, supportive, dependent, or adjunctive to the primary C-APC service?*

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(2) What integral, ancillary, supportive, dependent, or adjunctive items and services are routinely provided as part of the administration of cell and gene therapies or in conjunction with cell and gene therapies generally?

Separately, we also seek comment on whether policy revisions to the C-APC policy may be appropriate in future rulemaking, such as a modified outlier payment policy specific to C-APCs to address related situations in the future.

ASGCT greatly appreciates CMS' willingness to acknowledge the transformative nature of gene and cell therapies. Cell and gene therapies are re-shaping the landscape of treatment for rare diseases, offering unprecedented opportunities to impact the lives of patients who suffer from them. However, cell and gene therapies also represent a paradigm shift; rather than treating a disease with a lifetime of medications, cell and gene therapies typically involve a limited number of treatments. Medicare's traditional payment system must be modified to create greater certainty in the marketplace to ensure no patient experiences challenges in accessing the therapies. Furthermore, the Society appreciates that CMS' proposed rule explicitly acknowledges the nature of gene and cell therapies in the context of provider payment. Addressing issues related to consumer access moving forward necessitates acknowledgement of the challenges their nature creates for existing provider payments systems.

As noted earlier, ASGCT has historically expressed concern about the inclusion of the cost of gene and cell therapies in single, lump sum payments made to providers for their administration. Too often, these methodologies punish the provider administering the therapy by failing to accurately reflect the cost of the therapy. To that end, approaches that pay for the cost of the therapy separate from the cost of the associated care provided by the clinician and other ancillary services can help alleviate providers from undue financial stress.

ASGCT appreciates the constraints of the existing Medicare provider payment system. To that point, the Society was supportive of CMS' proposal to establish a separate DRG specific to the administration of CAR-T cell therapy in the Inpatient Prospective Payment System (IPPS), along with some of the other policies CMS has implemented to ensure the cases informing the relative weight of that DRG is reflective of the true costs incurred by providers. As CMS considers a methodology for a potential permanent C-APC policy, we encourage CMS to leverage the learnings from the process used in the IPPS when the first CAR T-cell therapies came to market. Among those lessons, we encourage CMS to use discretion in determining which cases should be used to inform the relative weight of C-APCs, particularly given the magnitude of the costs involved.

Thank you for the opportunity to submit comments on Medicare's proposed update to inpatient payments in FY 2025. Please contact Margarita Valdez Martínez, Chief Advocacy Officer, at mvaldez@asgct.org, with any questions.

Sincerely,

David M. Barrett, JD
Chief Executive Officer

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