May 10, 2025

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

Dear Administrator Oz:

The American Society of Gene and Cell Therapy appreciates the opportunity to comment on CMS-1833-P, the proposed rule for Medicare's Hospital Inpatient Prospective Payment System (IPPS) for 2026.

About ASGCT

The American Society of Gene and Cell Therapy (ASGCT) is a nonprofit professional membership organization comprised of more than 6,000 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 of sufficient and appropriate reimbursement levels to providers to facilitate patient access does not imply endorsement of any individual pricing decisions.

2026 Proposals

Refinements to MS-DRG 018

CMS received a request to "review the recent MS-DRG assignments to Pre-MDC MS-DRG 018…and to clarify how decisions for the assignment of cell and gene therapies will be made moving forward." This requestor suggested that there are "inconsistencies with the MS-DRG mappings of cell and gene therapy products in recent years" and "urged CMS to clarify how decisions for cell and gene therapies will be made in the future." In response, CMS provided an overview of current processes, while acknowledging "this category of therapies continues to evolve" and that CMS is "carefully

considering the feedback we have previously received about ways in which we can continue to appropriately reflect resource utilization while maintaining clinical cohere and stability in the relative weights under the IPPS MS-DRGs."

As ASGCT has shared with CMS in prior comment letters, we remain concerned about the uncertainty for new cell and gene therapies coming to market. To that end, we encourage CMS to be transparent in forthcoming in potential approaches to paying for new therapies.

ASGCT supported CMS' decision to establish a new DRG 018 for CAR T-cell therapy. The Society believes it was an appropriate step to ensure CMS would develop accurate coverage for this therapy. However, CMS has broadened the title of MS-DRG 018 to apply not just to CAR T-cell therapy but to other immunotherapies. Immunotherapies and gene therapies are distinct, and yet sometimes overlap in their approaches to treating cancer. CAR –Ts focus on modifying the genetic makeup of cells to target cancer directly- and traditional immunotherapies simply aim to boost the immune system without genetic modification. Adding other therapies to MS-DRG 018 could have significant consequences on the accuracy of payments for CAR T-cell therapies and other gene or cell therapies. If CMS were to assign higher volume, lower cost technologies to MS-DRG 018, it likely would distort the relative weight of the MS-DRG, potentially under-reimbursing autologous CAR-Ts.

CMS proposed to continue current policies related to relative weight calculations for MS-DRG 018. CMS has modified its methodology to exclude cases involving clinical trials, among other changes, and proposes to continue these approaches in 2026.

ASGCT appreciates that CMS continues to evaluate the methodology used to calculate the relative weight of MS-DRG 018 to reflect the unique nature of this DRG. For example, discounting cases involving clinical trials has helped CMS ensure that only those cases that include the cost of purchasing a CAR T-cell therapy are reflected in the relative costs used to set DRG 018.

New Technology Add-On Payment

The New Technology Add-On Payment (NTAP) is a critical tool for CMS to support patient access to new gene and cell therapies coming to market.

Cell and gene therapies are re-shaping the landscape of treatment for both rare and common 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. The limited number of treatments result in a pricing structure that differs significantly from traditional medicines and therapies.

In recent years, CMS has taken steps to acknowledge the unique nature of gene and cell therapies, following the approval of CAR T-Cell Therapy. CMS
took the step of establishing a new MS-DRG specifically for CAR T-cell therapy, despite the

relatively low volume of cases applicable to the DRG. However, before CMS established the DRG – CMS awarded the NTAP for two CAR T-cell therapy products. This decision provided a critical access bridge for these products, ensuring that providers could continue to make the products available to patients. This case study illustrates the importance of an effective NTAP policy in supporting patient access to new cell and gene therapies coming to market.

ASGCT offers the following recommendations for the NTAP program:

1. *CMS should establish multiple review periods for NTAP approval during the year.*

Establishing multiple periods for NTAP review and approval during the year, as well as beginning NTAP payments outside of the strict fiscal year cycle, would relieve much of the pressure associated with deadlines for the Fiscal Year rule cycle. Specifically, ASGCT recommends that CMS establish a quarterly review process for NTAP-qualifying products approved by the FDA, regardless of the approval pathway. The NTAP should be immediately accessible for new technologies coming to market and not be tied to an annual rulemaking cycle.

2. *Other recommendations*

- The ability for manufacturers to apply for NTAP when they have data to complete an NTAP application and CMS to "pend" those applications deemed to meet the applicable NTAP criterion until the product is marketed.

- An increase in the cap for NTAP amounts from 65 percent to 100 percent or a uniform NTAP equal to the product acquisition cost for gene and cell therapies. We appreciate the recent actions of CMS to increase the NTAP cap in FY 2020 from 50 percent to 65 percent, as well as the proposed changes specific to sickle cell therapies included in the FY 2025 proposed rule. However, even the 65 percent level would not be expected to sufficiently fill the gap in reimbursement to providers.

- NTAP eligibility for three full years to allow the increased collection of cost data for the small populations often treated by gene and cell therapies, prior to rate-setting, or establishing new MS-DRGs prior to NTAP expiration. Again, ASGCT appreciates CMS' to the effective date of the newness criteria proposed change in the FY 2025 rule in this spirit.
- Continue to recognize the limited patient populations (especially for products indicated for rare diseases) when considering the number of cases (excluding clinical trials cases) sufficient to establish a new DRG. Because the process for establishing new MS-DRGs is dependent upon CMS having sufficient data on charges for therapy, the creation of DRGs for gene and cell therapies for rare diseases with small populations can be delayed well past the NTAP period. If CMS intends to pay for future gene and cell therapies in a similar fashion to CAR T-Cell therapy through NTAP assignment as applicable, followed by the establishment of new DRGs, CMS must have flexibility in its metrics for such establishment.

American Society of Gene + Cell Therapy

Thank you for the opportunity to submit comments. Please contact Margarita Valdez Martínez, Chief Advocacy Officer, at mvaldez@asgct.org, with any questions.

Sincerely,

David Barrett, J.D.
Chief Executive Officer
American Society of Gene & Cell Therapy