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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-1807-P - Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

The American Society of Gene and Cell Therapy appreciates the opportunity to comment on CMS-1807-P, a proposed rule that would update the Medicare Physician Fee Schedule for 2025. We appreciate that the Centers for Medicare & Medicaid Services (CMS) is exploring separate payment for physician services related to the administration of gene and cell therapies. The complex process for administering gene and cell therapies involves multiple stages of clinician work with patients, including steps beyond the final administration of the cells. CMS' proposal is a welcome recognition of that complexity.

About ASGCT

The American Society of Gene and Cell Therapy (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 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 establish payment under the Physician Fee Schedule for four new CPT codes for services related to the administration of CAR-T cell therapies.

Specifically, CMS proposes to establish payment for 3X018-3X021, and set relative value amounts.

ASGCT appreciates CMS' proposal and request for comment regarding payment for services related to CAR T-Cell therapy under the Medicare Physician Fee Schedule.

Gene and cell therapies are re-shaping the landscape of health care delivery. The unique nature of the products offers a durable clinical benefit from a single administration, providing potentially life-changing benefits to patients suffering from a range of conditions. In the case of CAR-T cell therapy, these therapies offer the promise of new treatments for advanced cancers. More recently, the Food and Drug Administration (FDA) has approved two treatments for sickle cell disease. However, these unique therapies necessitate a unique, multi-step administration process. This process includes the collection of a patient's cells, treatment of the cells, and administration of the cells. In addition to these steps, providers offer care to patients for all the associated impact of patients receiving these therapies.

In the 2025 proposed rule, CMS includes some proposed changes that recognize the complexity of the full process associated with administering CAR-T cell therapies. Specifically, at the recommendation of the CPT Editorial Panel, CMS has proposed to strike:

- 0537T for collection/handling
- 0538T for transport
- 0539T for receipt and preparation
- 0540T for administration

In place, CMS proposes to establish:

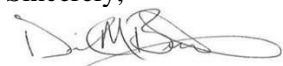
- 3X018 - harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
- 3X019 - preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
- 3X020 - CAR-T cell administration, autologous
- 3X021 - receipt and preparation of CAR-T cells for administration

ASGCT understands that CMS' proposal includes separate payment for the harvesting and preparation of patient cells, in addition to the administration of the final therapy. To that end, ASGCT is supportive of CMS' proposed coding change.

We also appreciate that CMS is seeking public comment on proposed work Relative Value Units (RVUs) and Practice Expense values for these codes. We encourage CMS to be receptive to feedback provided by clinicians in the comment process to ensure adequate payment for these services.

Thank you for the opportunity to submit comments on CMS' proposed update to the Medicare Physician Fee Schedule that would take effect in 2025. Please contact Margarita Valdez Martínez, Chief Advocacy Officer, at mvaldez@asgct.org, with any questions.

Sincerely,



David M. Barrett, JD
Chief Executive Officer