

September 9, 2024

VIA ELECTRONIC SUBMISSION

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1752-P
7500 Security Boulevard
Baltimore, MD 21244-1850

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 undersigned organizations, members of an informal working group focused on patient access to Chimeric Antigen Receptor (CAR) T-cell immunotherapies, are writing to express our appreciation for the Centers for Medicare & Medicaid's (CMS) continued leadership in supporting CAR T-cell therapies and to provide feedback on the FY2025 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (OPPS) proposed rule.

CAR T is a transformative therapy that substantially improves outcomes for patients with multiple forms of lymphoma, leukemia, and multiple myeloma and provides hope for many more with other hard-to-treat diseases. As more CAR T therapies are approved, patients are being treated with CAR T earlier, for new disease types, and in diverse settings.

Although administration of most CAR T-cell therapies has occurred in the inpatient setting in the past, advancements in treatment protocols and improvements in patient management are increasing outpatient administration.

Our Working Group believes that patients should have access to CAR T, in a safe, accessible environment, and we are concerned that patients are currently facing challenges accessing CAR T in outpatient settings. Ensuring availability of CAR T-cell therapy in the outpatient setting has the potential to significantly increase patients' access to these lifesaving treatments.

We thank CMS for its commitment to engaging stakeholder groups and we look forward to working with CMS as it considers additional feedback and suggestions to best manage payment policy and patient costs. We urge CMS to continue engaging with stakeholders on this matter in an open and transparent fashion.

We are pleased to offer the following comments and recommendations:

Concern for Future C-APCs for CAR T:

This working group is concerned that C-APC packaging for CAR T could exacerbate patient access challenges in the outpatient setting. We appreciate and agree with CMS' proposal to exclude the CAR T from packaging into Comprehensive APC (C-APCs) in CY 2025 and encourage CMS to finalize this change permanently despite the agency having proposed it for only one year.

Packaging CAR T and other cell and gene therapies could hinder patient access to these life-saving therapies in the outpatient setting by creating several clinical and operational hurdles. Specifically, the development of a C-APC for CAR T could create unfair and inadequate reimbursements to providers administering CAR T to patients in the hospital outpatient department setting, potentially increase the financial risk for beneficiaries when receiving CAR T, and detrimentally impact access in a way that would create more health equity challenges.

We recommend that CMS does not package any cell and gene therapies in C-APCs or another bundled payment policy for CAR T.

Additionally, we strongly encourage CMS to thoughtfully consider any significant reimbursement changes that could jeopardize care by creating additional barriers to access for CAR T in the outpatient setting.

Our organizations encourage CMS to consider the items raised above before the finalization of the proposed rule and look forward to working with CMS to further support novel treatments for unmet medical needs among cancer patients. For any questions, please contact ckoski@signaldc.com.

Sincerely,

American Society of Gene and Cell Therapy

Cancer Support Community

Health Tree Foundation