June 10, 2025

VIA ELECTRONIC SUBMISSION

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1833-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Quality Programs Requirements; and Other Policy Changes

Dear Administrator Oz,

The undersigned organizations, members of an informal working group focused on patient access to Chimeric Antigen Receptor (CAR) T-cell immunotherapies, write to thank the Centers for Medicare & Medicaid Services (CMS) for its continued leadership in supporting innovative oncology treatments. We also offer comments on the FY2026 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule.

CAR T-cell therapies have transformed cancer care for patients with aggressive blood cancers like lymphoma, leukemia, multiple myeloma, and chronic lymphocytic leukemia. They offer new hope to patients for whom traditional treatments have failed. CAR T is also beginning to show promise in other diseases such as lupus. As this class of therapies continues to grow, CMS policy must protect access to current treatments and provide a sustainable path forward for future innovation.

We applaud CMS for recognizing this innovative treatment with the creation of the Medicare Severity-Diagnosis Related Group (MS-DRG) 018 in 2021. We also appreciate CMS's ongoing thoughtful consideration of the MS-DRG 018 to ensure access for patients and the treatment's value to our healthcare system.

As stakeholders committed to ensuring patient access, we offer the following recommendations.

Protect the Integrity of MS-DRG 018

We urge CMS to safeguard the long-term viability of MS-DRG 018. As new therapies enter the market, some may have different clinical characteristics or lower resource intensity. Assigning these products to the same DRG risks skewing the relative weight and could jeopardize reimbursement levels for existing treatments.

We encourage CMS to increase transparency around the process for assigning new procedure codes to MS-DRGs, particularly for therapies in complex and evolving classes like CAR T. We support the development of a mechanism that allows stakeholders to understand and engage with DRG mapping decisions as part of, or in parallel to, the ICD-10-PCS code request process. Given

CMS's request for feedback on inclusion criteria, this is an important opportunity to ensure that each new therapy is evaluated based on clinical characteristics, resource intensity, and alignment with the DRG's intended scope. This is essential to maintaining both payment accuracy and coherence across the category.

Sustain and Improve the NTAP Pathway

The New Technology Add-On Payment (NTAP) program remains critical for accelerating access to breakthrough therapies.

We urge CMS to continue evaluating how the NTAP program can better support access to CAR T. A more flexible approach to assessing newness and clinical improvement would allow providers to offer treatments sooner and help ensure patients receive care when it matters most.

Additionally, we support NTAP approval for AUCATYZL (obecabtagene autoleucel), a CAR T therapy for relapsed or refractory B-cell acute lymphoblastic leukemia (R/R B-ALL), and for BREYANZI (lisocabtagene maraleucel) for relapsed or refractory chronic lymphocytic leukemia and small lymphoctyic lymphoma (CLL/SLL). These therapies represent critical advances for patient populations with few existing treatment options.

Address Persistent Gaps in Access

Although multiple CAR T therapies have been approved, access remains uneven. Patients in different geographies and care settings still face significant barriers. Most CAR T centers are in major cities, forcing many patients to travel long distances and navigate logistical challenges to receive care.[1] Data shows that if an eligible patients lives only 2-4 hours from an treatment center, the probability of them receiving CAR T therapy decreases by 40%.[2] These gaps must be addressed to ensure all eligible patients can benefit from these life-extending treatments.

CMS should explore changes that enable earlier adoption and broader access to CAR T. Potential solutions include expanded eligibility pathways, greater flexibility in the site of care, and the development of patient-focused quality measures. As the CAR T class expands, payment policy must keep pace with innovation while prioritizing fairness and access.

We encourage CMS to take this opportunity to place markers for future improvements that can support broader access and sustained innovation.

We thank CMS for its ongoing efforts to ensure access to cutting-edge treatments and for the opportunity to provide input. We urge the agency to protect MS-DRG 018, modernize the NTAP process, and support broader adoption of CAR T-cell therapies.

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[1] Mikhael J, Fowler J, Shah N. Chimeric Antigen Receptor T-Cell Therapies: Barriers and Solutions to Access. JCO Oncol Pract. 2022;18(12):800-807. doi:10.1200/OP.22.00315. Epub September 21, 2022. PMID: 36130152.

[2] Ahmed N, Sun F, Teigland C, et al. Chimeric antigen receptor T-cell access in patients with relapsed/refractory large B-cell lymphoma: association of access with social determinants of health and travel time to treatment centers. Transplant Cell Ther. 2024;30(7):714-725. doi:10.1016/j.jtct.2024.04.017

We look forward to continued collaboration on these critical issues. For any questions, please contact ckoski@signaldc.com.

Sincerely,

American Society of Gene & Cell Therapy
BMT Infonet
Cancer Support Community
HealthTree Foundation
International Myeloma Foundation
Lymphoma Research Foundation