June 10, 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: Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes

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 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule.

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

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.

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:

<u>Concern for Long Term Health of DRG</u>

We continue to be concerned for the long-term viability of MS-DRG 018 as more novel products enter the market.

As CMS has noted, MS-DRG 018 currently has assigned a wide variety of technologies with varying resource intensities. If CMS were to continue to assign new, higher volume, lower cost therapies to MS-DRG 018, it could potentially distort the relative weight of MS-DRG, under-

reimbursing CAR Ts. Given this, we recommend that CMS does not map prademagene zamikeracel to MS-DRG 018 due to the clinical resource differences between it and the other therapies that are currently mapped to this MS-DRG.

We commend CMS for maintaining the clinical trial condition code and removing the claims when calculating the average cost for MS–DRG 018 and we agree with CMS' decision not to modify the current title of the MS-DRG 018.

Given the important role these treatments play and will continue to play for cancer patients, we encourage CMS to clarify its methodology for the inclusion of new procedure codes within MS-DRG 018 and to consider the cost and resources needs of potential new additions to MS-DRG 018 as to not harm access to current therapies.

Concern for New Technology Add-On Payment (NTAP) Approval Timeline

CMS's NTAP documentation and timeline changes included in the FY2024 Final Rule resulted in more products having to be on the market longer for NTAP payments to begin. Providers rely on NTAP to be able to provide access to new and innovative medicines, and this change delayed access to critical therapies for patients.

We appreciate CMS' proposed changes in the 2025 proposed rule adjusting the date from April 1 to October 1 to determine whether a product is within its 2-to-3-year newness period. However, it does not ensure that most CAR Ts will receive three years of NTAP payments.

Additionally, as CMS considers new products for NTAP status, we encourage the inclusion of clinical differences in targets and delivery mechanisms to be considered in the newness and substantial clinical improvement criterion. Many of these therapies offer opportunities for patients who have historically had limited treatment options available to them.

We encourage CMS to ensure revisions to the NTAP rule maximize access to products as soon as they are available, and for the full 3 years. This is essential to ensure more patients have access to CAR Ts in the future.

Health Equity Quality Measures

We applaud CMS's commitment to health-equity-related measures and its continued efforts to close the gap in racial equity and in underserved communities. We are encouraged by CMS's willingness to solicit feedback on how it can improve its use and breadth of health equity measures.

We encourage CMS to include the voices of patients from different backgrounds to facilitate a greater understanding of the patient perspective of CAR T treatments as it considers and determines future rulemaking or guidance to advance health equity.

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 & Cell Therapy

Cancer Support Community

HealthTree Foundation

International Myeloma Foundation

Leukemia & Lymphoma Society

Lymphoma Research Foundation