

June 9, 2023

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 Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership

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 FY2024 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, and multiple myeloma and provides hope for many more with other hard-to-treat cancers. 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:

Concern for Long Term Health of DRG

We continue to be concerned for the long-term viability of MS-DRG 018 as more novel products enter the market. If CMS were 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 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 proposed changes could have significant implications for the availability and duration of add-on payments. By requiring FDA approval by May 1, the proposed change could reduce the duration of NTAP from three years to two years. Providers rely on NTAP to be able to provide access to new and innovative medicines.

We encourage CMS to consider maintaining the existing timeline as reducing the duration of NTAP could significantly reduce patient access to therapies like CAR T.

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,

The American Society of Gene and Cell Therapy

Cancer Support Community

The Leukemia & Lymphoma Society

HealthTree Foundation

International Myeloma Foundation