

June 17, 2022

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; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation.

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 Center for Medicare and Medicaid's (CMS) actions to support CAR T-cell therapies and to provide feedback on the FY2023 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule.

CAR T represents 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 the science evolves, patients are being treated with CAR T earlier, for new disease types, and in diverse settings.

The field of cell and gene therapies continues to grow, with CAR T leading the way. CAR T-cell therapies remain the most common technology used in the pipeline of genetically modified cell therapies (preclinical through to pre-registration), representing 49% of technologies¹. The development pipeline contains future cell therapies which will provide greater ease for patients, providers, and caregivers, and target some of today's most difficult to treat cancers.

We would like to thank CMS – and specifically, CMMI's Chris Ritter – for speaking with our stakeholders and for its continued engagement with our CAR T Working Group. We encourage continued partnership with industry, patients, providers, and other stakeholders to consider the therapeutic landscape and how CMS can ensure access to transformative CAR T therapy in the future.

¹ <https://asgct.org/global/documents/asgct-pharma-intelligence-q1-2022-report.aspx>

We are pleased to offer the following comments and recommendations:

Innovative and Meaningful Action from CMS to Support Patient Access to CAR T

- We applaud CMS for recognizing CAR T as an innovative product with the creation of the Medicare Severity-Diagnosis Related Group (MS-DRG) 018 in 2021, and its ongoing thoughtful consideration of the MS-DRG 018 to ensure access for patients, and value to our healthcare system.
- 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 resource needs of potential new additions to MS-DRG 018 as to not harm access to current therapies.
- Additionally, we are supportive of CMS' proposed cap on the MS-DRG base payment adjustment and look forward to working with CMS to ensure rate fluctuation does not impact patient access.

Continue and Increase Stakeholder and Patient Engagement

- We thank CMS for its commitment to engaging stakeholder groups and look forward to working with CMS as it considers additional feedback and suggestions to best manage coverage and payment policy and patient costs. We urge CMS to continue engaging with stakeholders on this matter in an open and transparent fashion.
- We appreciate CMS's willingness to engage patient groups on novel and expedited approaches to gene and cell therapy product development, and we recommend increased engagement with patient groups to facilitate a greater understanding of the patient perspective of CAR T treatments.
- We are encouraged by CMS's willingness to explore creative policy solutions for rare diseases and conditions, and welcome participation in the process to ensure access to inpatient care for these patients.

Consider New Technology Add-On Payment (NTAP)

- We encourage CMS to consider assigning New Technology Add-on Payments (NTAPs) for new CAR T therapies, including ciltacabtagene autoleucel, to ensure patients can access treatment.

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 Cancer Society Cancer Action Network, Inc.

American Society of Gene and Cell Therapy

BMT InfoNet

Cancer Support Community

CLL Society

HealthTree Foundation

International Myeloma Foundation

The Leukemia & Lymphoma Society