

July 9, 2020

VIA ELECTRONIC SUBMISSION

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1735-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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals.

Dear Administrator Verma:

The undersigned organizations are writing to express our support for the establishment of new Medicare Severity-Diagnosis Related Group (MS-DRG) for Chimeric Antigen Receptor (CAR) T-cell Immunotherapy. CAR T represents transformative therapy that substantially improves outcomes for patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) and B-cell acute lymphoblastic leukemia (ALL) and provides hope for many more with other hard-to-treat cancers. The Centers for Medicare & Medicaid Services' (CMS) proposal recognizes the importance and value of these therapies and serves as incentive for further development in this arena.

The proposed rule specifically calls for terminating the New Technology Add-on Payments for the two currently approved CAR T products and transferring them to a newly created MS-DRG 018 with a base payment for Fiscal Year 2021. In setting this payment rate, CMS further proposes not to use the claims data generated from patients in clinical trials and recognizes the limited data set available.

We applaud CMS' understanding that CAR T therapies represent a truly innovative product and necessitate the need to create a new DRG, notwithstanding the limited patient population to date. The current data set is limited due partially to provider uncertainties regarding the existing reimbursement formulas. This suggests that the current reimbursement rate has been a barrier to more widespread use of CARTs, potentially limiting access and additional data collection.

The new MS-DRG will yield significant benefits and outcomes for patients, providers and hospitals nationwide as providers will have another course of treatment and hospitals will be able

to offer it. Further, a recent study demonstrated that lymphoma patients experienced significant improvements in their physical, social, and emotional health following CAR T treatment.¹

Our organizations commend CMS for its action and appreciate its forward-leaning policy proposal that will optimize patient access for CAR T therapy. We support finalization of the proposed rule and look forward to working with CMS to further support novel treatments for unmet medical needs among immunotherapy patients. For any questions, please contact Kim Czubaruk, Esq., Senior Director, Policy & Advocacy, Cancer Support Community.

Sincerely,

American Cancer Society Cancer Action Network

BMT Infonet

Cancer Support Community

CLL Society

CrowdCare Foundation / Myeloma Crowd

International Myeloma Foundation

Leukemia & Lymphoma Society

Lymphoma Research Foundation

Society for Immunotherapy of Cancer (SITC)

The Pink Fund

¹ Richard T. Maziarz, et al. Patient-reported long-term quality of life after tisagenlecleucel in relapsed/refractory diffuse large B-cell lymphoma. Blood Advance. 19 Feb. 2020.