Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1694-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program: Hospital Inpatient Prospective Payment Systems FY19 Proposed Rule (CMS-1694-P)

Dear Administrator Verma:

The Society for Immunotherapy of Cancer (SITC) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS') Medicare Program: Hospital Inpatient Prospective Payment Systems FY19 Proposed Rule. With nearly 2,000 members representing 17 medical specialties, SITC is the world's leading member-driven organization specifically dedicated to improving cancer patient outcomes by advancing the science and application of cancer immunotherapy. SITC aims to increase the standard of care applications of cancer immunotherapy, and thus supports efforts to ensure maximal patient access to these life-saving therapies.

SITC would like to comment specifically on two areas of the IPPS proposed rule for fiscal year 2019: II – F. Proposed Changes to Specific DRG Classifications: 2. d. CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY, and II – H. Proposed Add-On Payments for New Services and Technologies for FY 2019: 5. a. KYMRIAH (Tisagenlecleucel) and YESCARTA (Axicabtagene Ciloleucel).

II – F. Proposed Changes to Specific DRG Classifications: 2. d. CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY

First, we would like to propose revising the title of MS-DRG 016 from "Autologous Bone Marrow Transplant with CC/MCC" to "Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy." Second, we are aware that CMS is proposing to assign ICD-10-PCS procedure codes XW033C3 and XW043C3 to Pre-MDC MS-DRG 016 for FY 2019. SITC is opposed to this proposed change and instead recommends the establishment of a new MS-DRG specifically for CAR-T therapies. While we understand that CMS is trying to remove outdated and redundant regulations on providers and reward value over volume, the current Medicare reimbursement rates and proposed MS-DRG 0016 rate for Autologous Bone Marrow Transplant *incorporating T-Cell Immunotherapy* are not sufficient for hospitals to cover the high drug-related costs of acquiring specialized and effective CAR-T therapies.

CAR-T therapies remain relatively new to the field, and researchers are still working to understand how best to administer these novel therapies and manage side-effects. Despite this novelty, however, clinical administration of CAR-T therapy has provided clear differentiation from autologous bone marrow transplant. SITC believes that both resource consumption and clinical characteristics of the patients who receive CAR-T therapies are significantly different than patients in the MS-DRG treated with autologous bone marrow transplant.

Concerning resource consumption, the patient care cost and inpatient duration for CAR-T versus autologous bone marrow transplant is not comparable. FDA approved CAR-T therapies require only a singular infusion in either inpatient or outpatient settings, and the setting drastically alters overall cost. We believe it to be necessary for any MS-DRG to be able to differentiate and adapt to inpatient/outpatient options and feel that combining CAR-T therapies into the proposed MS-DRG will hinder that distinction. Concerning patient populations, clinical application of CAR-T therapies is vastly different compared to autologous bone marrow transplant, so much so that the approaches are often used in tandem or sequence. For example, in the confirmatory study that resulted in FDA approval of YESCARTA, many patients treated with CAR-T had relapsed after receiving autologous bone marrow transplant[1]. Furthermore, clinicians continue to study the clinical benefit of transplant after CAR-T, further proving that these two technologies are complementary rather than interchangeable[2].

SITC urges CMS to **create a separate MS-DRG for CAR-T cell acquisition costs** to allow for technicalities and adjustments as further and rapid advances occur not only in the clinical space, but also concerning drug pricing. We believe that a separate MS-DRG would provide CMS greater flexibility to respond to these changes and adjust cost-to-charge ratios (CCR), which would lead to a more accurate wage index and improved reimbursement levels. Finally, the number of patients treated with CAR-T continues to grow as the field advances, and will soon be substantial enough to warrant a separate MS-DRG.

II – H. Proposed Add-On Payments for New Services and Technologies for FY2019: 5.a. KYMRIAH (Tisagenlecleucel) and YESCARTA (Axicabtagene Ciloleucel)

SITC supports New Technology Add on Payments (NTAP) for KYMRIAH and YESCARTA to increase patient access. There are a growing number of CAR-T cell therapies being developed, with over 100 clinical trials in 2017 alone[3]. The substantial clinical improvement and the long-term curative potential of CAR-T therapies has been demonstrated in studies reported as recently as June 2018[4]. In general, immunotherapy was the last resource for cancer patients who had already exhausted all other options such as radiation, targeted therapy and chemotherapy, and yet, immunotherapy provided not only relief but remission if not cure to many individuals with otherwise rapidly terminal illnesses. Today, immunotherapy treatments such as CAR-T cell therapy are increasingly used in earlier settings of disease given the rapid advances in cell transfer clinical development. Ultimately, as research continues to rapidly expand and more FDA approvals are granted, more patients will be spared the application of less effective therapies and more lives will be saved.

Both KYMRIAH and YESCARTA meet the newness and substantial clinical improvement criterion required for NTAP approval. It should be recognized, however, that KYMRIAH and YESCARTA are not substantially similar to existing technologies. Primarily, we believe CMS should more closely evaluate and analyze

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[1] Neelapu SS, Locke FL, Bartlett NL, Lekakis LJ, Miklos DB, Jacobson CA, Braunschweig I, Oluwole OO, Siddiqi T, Lin Y *et al*: **Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma**. *N Engl J Med* 2017, **377**(26):2531-2544

[2] Shalabi H DC, Stetler-Stevenson M, et al.: **Chimeric antigen receptor t-cell (CAR-T) therapy can render patients with all into PCR-negative remission and can be an effective bridge to transplant (HCT).** *Poster 1017. 2018 ASPHO Conference; May 2-5, 2018; Pittsburgh, PA.*

[3] Jansson, Felix, Shedding light on the CAR-T space – research, clinical activity and targets of interest, Monocl, February 20, 2018, retrieved online from https://www.monocl.com/through-the-lens/shedding-light-car-t-space/

[4] Locke FL, Ghobadi A, Jacobson CA, Jacobsen ED, Miklos DB, Lekakis LJ, Braunschweig I, Oluwole OO, Lin Y, Siddiqi T *et al*: Durability of response in ZUMA-1, the pivotal phase 2 study of axicabtagene ciloleucel (Axi-Cel) in patients (Pts) with refractory large B-cell lymphoma. *Journal of Clinical Oncology* 2018, 36(15_suppl):3003-3003.

reimbursement options and provide the flexibility of CAR-T infusions occurring in either inpatient or outpatient settings.

Again, we appreciate the opportunity to submit our comments on CAR-T therapy IPPS proposed reimbursement and welcome the opportunity to serve as a resource to CMS on key elements for operationalizing CAR-T. We respectfully offer our society's leadership and expertise in future considerations impacting the field of cancer immunotherapy.

Should you have any questions, please do not hesitate to contact SITC Executive Director, Tara Withington, at twithington@sitcancer.org.

Sincerely,

Lisa H. Butterfield, PhD
SITC President