June 24, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
CMS-1716-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: FY2020 Proposed IPPS Rule

Dear Administrator Verma:

The Society for Immunotherapy in Cancer (SITC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services’ (CMS) proposed Inpatient Prospective Payment System (IPPS) rule for fiscal year 2020. SITC is the world’s leading member-driven organization specifically dedicated to improving cancer patient outcomes by advancing the science, development and application of cancer immunology and immunotherapy. SITC strives to make cancer immunotherapy a standard of care and the word “cure” a reality for cancer patients everywhere.

SITC appreciates CMS’ continued support of cancer patients with CAR-T therapy which has demonstrated proven efficacy in several clinical trials and which have led to FDA approval of two CAR-T therapies.1,2 We believe that CAR-T is just the latest in what will be a long line of successful cancer immunotherapy treatments. Therefore, it is imperative that CMS establish a fair and adequate reimbursement rate for participating CAR-T delivery sites. Failure to do so could jeopardize patient access to care and stifle further innovation in this breakthrough area.

In particular, we appreciate CMS’ proposal to increase the New Technology Add-on Payments (NTAP) to 65 percent of the drug acquisition price for all therapies, including CAR-T. SITC believes that this increase is a step in the right direction for PPS providers. However, SITC recognizes three primary issues with the existing NTAP, even with the proposed increase.

- First, the NTAP is time limited and CAR-T therapies will no longer be eligible starting as early as FY21, indicating that this increase provides only a short-term solution.
- Second, many eligible hospitals do not regularly receive the full NTAP, which further poses access barriers to a potentially life-saving therapy.
- Third, the NTAP as designed does not account for the intensity of inpatient hospital care associated with these groundbreaking therapies. As such, SITC believes a longer-term, more inclusive solution is necessary to ensure all providers can continue to offer revolutionary CAR-T therapies to eligible Medicare beneficiaries.

Consider a separate MS-DRG
We would suggest that CMS create a new MS-DRG specifically for CAR-T. This is a reasonable long-term solution and one that could help ensure a more adequate reimbursement rate for providers. As CMS has pointed out before, more data is needed before a new MS-DRG can be created. Therefore, we would ask that the NTAP continue until a new MS-DRG can be established.

Consider PPS-exempt centers
However, an increased NTAP, and even a new MS-DRG, still does not help PPS-exempt cancer hospitals who receive even less reimbursement for treating CAR-T patients as these centers rely on payments dictated by the Tax Equity and Fiscal Responsibility Act (TEFRA). SITC wants to ensure that as many patients as possible will have access to these highly effective treatments, regardless of treatment center PPS status. Therefore, SITC believes that efforts should simultaneously be made to increase the so-called “TEFRA ceiling” to account for the added costs of a breakthrough drug like CAR-T to PPS-exempt centers. SITC also favors an improved appeals process for the PPS-exempt centers, so that questions around CAR-T billing may be resolved in a timely manner.

As CMS tries to set an appropriate reimbursement for CAR-T, SITC members are watching CMS’ work with interest because in many ways, the decisions around CAR-T could be a harbinger of future reimbursement issues for other immunotherapies. Many of SITC’s members are on the front lines developing the next generation of immunotherapies that could cure cancer. We feel it is important that CMS develop a long-term framework for immunotherapy reimbursement as to be prepared for when the next wave of groundbreaking treatments arrive in the clinic. We understand that CMS must take into consideration many different factors when setting payment rates for these treatments, but we would also ask that you take into consideration the value of providing immunotherapy to cancer patients. Immunotherapies have demonstrated that they can provide more durable responses to cancer patients compared to other treatment modalities, while simultaneously being generally less toxic and providing patients an improved quality of life during treatment.

Thank you again for the opportunity to submit comments on the proposed FY20 IPPS rule. We would ask that you please give our comments every due consideration as you formulate the final rule.
Should you have any questions, please do not hesitate to contact SITC Executive Director, Tara Withington, at twithington@sitcancer.org.

Sincerely,

Tara Withington, CAE,
Executive Director, Society for Immunotherapy of Cancer