



July 10, 2020

The Honorable Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services

RE: CMS-1735-P; FY2021 Proposed IPPS Rule

Dear Administrator Verma:

The Society for Immunotherapy in Cancer (SITC) appreciates the opportunity to provide comment on the proposed changes to the proposed Inpatient Prospective Payment System rule for fiscal year 2021 (FY21 IPPS). 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.

We commend the Centers for Medicare and Medicaid Services' (CMS) for the creation of a new diagnosis-related group (DRG) for Chimeric Antigen Receptor (CAR)-T cell Therapies. SITC appreciates that CMS listened to various stakeholders across the field and enacted steps to create this new DRG, and strongly believe that the inclusion of this CAR-T specific DRG will greatly enhance access of these life-saving treatments to patients across the country. In addition, we specifically thank CMS for enacting many innovative and thoughtful processes to create this new CAR-T specific DRG, including utilizing a limited number of data, as well as ensuring that outlier and clinical trial cases were not included in the necessary reimbursement calculations, thus providing centers rapid yet comprehensive reimbursement for these treatments.

As a society rooted in all facets of immunotherapy, SITC hopes that the proposed changes within the FY21 IPPS rule will serve as precedent for future immunotherapy treatments. Our volunteers recognize that CAR-T therapies are simply the "next step" in what will likely be a long line of successful cancer immunotherapy treatments. SITC projects that new modalities, as well as new CAR-T strategies, will continue to enter the clinic at an unprecedented rate. As such, we emphasize that CMS will need to ensure that novel data analyses used for the creation of the CAR-T DRG – leveraging limited data and excluding outlier cases – become widely adopted as new treatments become available.

We recognize that the New Technology Add-on Payment (NTAP) is in place to help serve as a conduit as new treatments enter the clinic. However, the CAR-T experience revealed that many centers do not receive full and necessary reimbursement via this mechanism. Therefore, we would encourage CMS to explore the development of a framework for future cellular immunotherapy reimbursement. SITC would be pleased to help CMS with this initiative and would offer the assistance of our expert opinion leaders. We could also serve as a convener of

other similarly-situated associations, as well as other government entities, including Congress, the US Food and Drug Administration, and the National Cancer Institute, to develop a framework for collaborative drug development and reimbursement strategies.

Lastly, SITC envisions that the creation of this new CAR-T specific DRG presents an opportunity to collect data that would aid development of national quality benchmarks. There are relatively few quality measures available concerning CAR-T treatments and other immunotherapies, creating variable care across the field. We encourage CMS to collaborate with stakeholders in order to maximize the development of quality measures based on this newly available data collection opportunity. SITC has experience in quality measure concept development, and would be happy to participate in or lead any efforts leading to the creation of quality measures for CAR-T therapies and other immunotherapies.

Thank you again for adopting stakeholder comments for the development of the proposed FY21 IPPS rule. SITC fully supports the proposal to create a CAR-T specific DRG and would encourage you to include the new DRG in the final IPPS rule. Should you have any questions, please do not hesitate to contact SITC Executive Director, Tara Withington, at [twithington@sitcancer.org](mailto:twithington@sitcancer.org).

Sincerely,

A handwritten signature in cursive script that reads "Tara Withington".

Tara Withington  
Executive Director, Society for Immunotherapy of Cancer