

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1784-P, Mail Stop C4-26-05 7500 Security Blvd Baltimore, MD 212244-1850

Re: CMS-1786-P: CY 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Brooks-LaSure:

The Society for Immunotherapy of Cancer (SITC) appreciates the opportunity to comment on the *Calendar Year (CY) 2024 Outpatient Prospective Payment System (OPPS) Proposed Rule.* 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. For decades, SITC members have been at the forefront of cancer immunotherapy research working to develop and advance novel therapeutics into the clinic for the treatment of various cancers, including modalities such as CAR T-cell that are heavily discussed within the proposed rule.

SITC is pleased to provide comment to CMS focused on the impact of the proposed rule upon CAR T-cell therapy reimbursement, as well as the potential precedent that may be set for future novel immunotherapies administered in outpatient settings. These comments are in parallel with other professional societies and represent our membership's recommendations on how the rule may better serve immunotherapies both currently and into the future:

- SITC supports mapping CAR T-cell revenue codes to cost centers: SITC appreciates efforts made by CMS to finalize mapping of CAR T-cell revenue codes to cost centers. Our volunteers have been at the forefront of CAR T-cell therapy administration and have voiced concern over reimbursement procedures limiting patient access and vital, life-saving care. SITC believes that finalization of revenue code mapping will help to ensure more accurate accounting of the true costs of CAR-T therapies within OPPS and provide more timely and appropriate reimbursement to support patient access.
- SITC recommends reevaluation of how CAR T-cell therapies may be impacted by C-APC packaging: CAR T-cell therapies are advanced novel drugs that when delivered within the outpatient setting may occasionally require monitoring for advanced adverse events. When this occurs, C-APC (8011) may be triggered and provide insufficient payment for CAR T-cell therapy.

- SITC encourages CMS to reevaluate the impact of CAR T-cell therapy upon current C-APCs to ensure that appropriate reimbursement is provided under these scenarios.
- SITC emphasizes the importance of setting precedent via the CAR T-cell experience: SITC is confident that our volunteers will discover future breakthroughs that will lead to novel immunotherapeutics entering the clinic for the treatment of patients with various malignancies. As such, SITC has been heavily invested in ensuring appropriate reimbursement for CAR T-cell therapy in both IPPS and OPPS proposed rules as these efforts will serve as a foundation for future immunotherapies that also require rapid and sufficient reimbursement to support life-saving patient access. SITC appreciates the efforts by CMS to provide appropriate reimbursement for CAR T-cell therapy and emphasizes the importance of these efforts being foundational for future novel agents.

We thank CMS for providing an opportunity to deliver comment on the proposed rule. As the field of immunotherapy continues to advance and these agents become standard of care across numerous disease states, SITC encourages CMS to engage with SITC on how reimbursement can impact quality of care and access for patients. SITC is committed to delivering the highest quality of care to cancer patients across the country. Should you have any questions, please do not hesitate to contact me at mdean@sitcancer.org.

Sincerely,

Mary Dean, JD, CAE Executive Director

Society for Immunotherapy of Cancer