AMERICAN SOCIETY of GENE & CELL THERAPY

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
P.O. Box 8011, Baltimore, MD 21244-1850

Attention: CMS-1694-P: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates

Dear Administrator Verma:

The American Society of Gene and Cell Therapy (ASGCT) appreciates the opportunity to comment on CMS-1694-P. ASGCT is the premier membership organization representing over 2,900 scientists, physicians, and other professionals in gene and cell therapy. A core portion of the Society's mission is to advance the discovery and clinical application of genetic and cellular therapies to alleviate human disease. ASGCT therefore supports efforts to maximize patient access to approved therapies, including the implementation of reimbursement mechanisms that could foster patient access.

These comments will focus on two areas of significance to ASGCT members and the patients who have the opportunity to benefit directly from access to CAR T-cell therapies for the treatment of certain types of acute lymphoblastic leukemia (ALL) and lymphoma:

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

II – H. Proposed Add-On Payments for New Services and Technologies for FY 2019:
5. a. KYMRIAH (Tisagenlecleucel) and YESCARTA (Axicabtagene Ciloleucel)

The level that Medicare reimburses for CAR T-cell therapy through current mechanisms often leaves a significant gap in payment to PPS hospitals compared to their combined costs for services and for the biologic therapy, creating high risk of substantial financial losses to hospitals for providing the therapy. Some hospitals that had planned to become authorized treatment centers have not yet started providing CAR T-cell therapy as of May 22, 2018, and ASGCT is concerned that such losses may be unsustainable for providers. This situation poses potential barriers to patient access to these therapies by decreasing the already limited prospective number of authorized treatment centers, and potentially affecting the proximity of treatment to seriously ill cancer patients.

ASGCT therefore strongly appreciates that CMS has acknowledged stakeholder concerns about this problem in the 2019 IPPS proposed rule. The proposals offered in the plan for

PPS hospitals would provide improvement to the current state of reimbursement levels. ASGCT supports an option that has the potential to best enhance patient access through adequate reimbursement of CAR T-cell therapies in FY2019, detailed below.

Assignment of CAR T-Cell Procedure Codes to an Existing DRG or a New CAR T-Cell DRG

CMS notes in the proposed rule that its clinical advisors believe that patients receiving treatment utilizing CAR T-cell therapy procedures would have similar clinical characteristics and comorbidities to those seen in cases representing patients receiving treatment for other hematopoietic carcinomas who are treated with autologous bone marrow transplant therapy that are currently assigned to MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC). CMS is therefore proposing to assign ICD-10-PCS procedure codes XW033C3 and XW043C3 to Pre-MDC MS-DRG 016 for FY 2019, with revision of the title of that MS-DRG to "Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy."

ASGCT supports this DRG assignment at the current time. While patients receiving CAR T-cell therapy differ from patients receiving autologous bone marrow transplantation, the number of patients who have received CAR T-cell therapy to date is likely insufficient to meet the CMS preference not to create a new DRG unless it would include a substantial number of cases. This criterion is likely to be met in the future, at which time ASGCT would support the establishment of a new DRG that would adequately describe and account for the delivery of CAR T-cell therapies. In the interim, it is essential that patients have immediate access to these potentially lifesaving therapies.

Payment Alternatives

ASGCT appreciates that CMS is inviting public comment on additional payment alternatives. The alternative that ASGCT supports as the most likely to provide the most appropriate reimbursement level would be to pay the drug acquisition cost separately as a pass-through payment (the average sales price), with no change to the outlier determination except removal of the product cost from the calculation.

This reimbursement method would also promote comparability between the inpatient and outpatient settings. The labeled uses of CAR T-cell therapies do not specify the setting in which the therapy is to be performed,[1,2] and clinical trials have been performed in both the inpatient and outpatient settings.[3] Comparability in payment for CAR T-cell therapies across both settings is significant in that it would encourage the safety and medical needs of individual patients through selection of the setting for the procedure on an individual basis, without the potential for cost considerations.

Because CMS has provided Transitional Pass-Through (TPT) payment for CAR T-cell therapies provided on an outpatient basis, a greater reimbursement level is currently provided for outpatient administration (unless a patient needs to be hospitalized within 72 hours). Greater parity between inpatient and outpatient reimbursement levels would be created through payment of inpatient drug

[1] Kite Pharma, Inc. (2017). *Yescarta: Prescribing information.* Santa Monica, CA.
[2] Novartis. (2017). *Kymriah: Prescribing information.* East Hanover, NJ.
[3] Schuster, S.J., Bishop, M.R., Tam, C.S, et al. (2017). Aggressive lymphoma (diffuse large B-cell and other aggressive B-cell non-Hodgkin lymphomas)—results from prospective clinical trials: immune-based therapeutic approaches. In *Proceedings from the 59th Annual Meeting and Exposition of the American Society of Hematology*. Paper presented at the 59th Annual Meeting and Exposition of the American Society of Hematology, Atlanta, December 9-12.

acquisition costs as pass-through payments as well. A similar approach is being used for CAR T-cell therapy reimbursement by some state Medicaid programs, such as the state of New York,[4,5,6] and has precedent in the Medicare reimbursement of hemophilia blood clotting factors.

New Technology Add-On Payments

We also appreciate CMS' consideration of New Technology Add on Payments (NTAP) for the two approved CAR T-cell therapies. If reimbursement were to be provided as outlined above, with the drug acquisition cost reimbursed in addition to the existing DRG, an NTAP payment would not be indicated as it would not meet the cost criterion. If CMS does not adopt the preferred reimbursement method above, providing an NTAP approval and utilizing a CCR (cost-to-charge ratio) of 1.0 in the determination of outlier payment would enhance current reimbursement levels, but not as adequately as the method described above. Under these conditions, the therapies under consideration would meet CMS criteria for NTAP consideration. CAR T-cell therapies provide substantial clinical benefit, as documented in the proposed rule by the applicants, and these therapies would meet the cost criterion based on the analyses by both the applicants and CMS contained in the proposed rule. CAR T-cell therapies also meet the newness criterion for NTAP consideration. ASGCT agrees with the applicant in response to the CMS concern that the mechanism of action for Yescarta may be the same or similar as the Bi-Specific T-Cell Engagers (BiTE) technology. As stated by the applicant, BiTE technology is not an engineered autologous T-cell immunotherapy derived from a patient's own T-cells. Unlike engineered T-cell therapy, BiTE does not have the ability to enhance the proliferative and cytolytic capacity of T-cells through ex-vivo engineering.

Value-Based Care and Drug Costs

In the proposed rule, CMS invites comments on value-based care and lower drug prices. Value-based payment contracts made by individual manufacturers with CMS would not be limited by any of the options for enhancing Medicare reimbursement levels. Such value-based contracting offers the advantage to payers of tying payment to the outcomes of the therapy, so that lower costs are incurred for less effective individual patient results, which ASGCT supports as a voluntary option for manufacturers. With respect to drug costs, other organizations have concluded that CAR T-cell therapies are, in fact, cost effective.[7] Moreover, ASGCT promotes future innovation in the development, manufacturing, and delivery of CAR T-cell therapies that may create efficiencies and reduce costs.

---

[4] New York State Department of Health. (2017). New York State Medicaid Update, Volume 33, Number 11. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2017/201711.htm#tisagenlecleucel. Accessed May 6, 2018.

[5] New York State Department of Health. (2018). New York State Medicaid Update, Volume 34, Number 1. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2018/2018-01.htm#yescarta. Accessed May 6, 2018.

[6] New York State Department of Health. (2018). New York State Medicaid Update, Volume 34 - Number 3. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2018/2018-03.htm#luxturna. Accessed May 6, 2018.

[7] Institute for Clinical and Economic Review. (2018). Chimeric antigen receptor T-cell therapy for B-cell cancers: Effectiveness and Value. Available at: https://icerreview.org/wpcontent/uploads/2017/07/ICER_CAR_T_Final_Evidence_Report_032318.pdf. Accessed May 6, 2018.

Conclusion

ASGCT appreciates the thoughtful consideration CMS is affording the classification and reimbursement structure for approved CAR T-cell therapies. To summarize, ASGCT supports CMS implementation of the following option that appears most likely to offer the most adequate reimbursement of, and therefore patient access to, CAR T-cell therapies:

> Assignment to MS-DRG 016, with the acquisition cost (average sales price) paid as a pass-through payment (with no change to the outlier determination except for removal of the product cost from the calculation)

ASGCT encourages reimbursement decisions to continue to evolve and incorporate new payment models that ensure that patients are able to access these breakthrough treatments. We stand ready to work with CMS and other stakeholders to develop models that optimize the availability and access of patients to approved gene and cell therapies. Please let us know if you have any questions for which we may be of guidance.

Sincerely,

Michele Calos, PhD
President