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Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1716-P
7500 Security Boulevard
Baltimore, MD 21244

5. Proposed Adoption of electronic Clinical Quality Measure, Use of Opioids – Concurrent Prescribing
6. Sanofi NTAP Application for Cablivi

CAR-T Reimbursement Recommendation for FY 2020 IPPS

CMS requested comments on payment alternatives for chimeric antigen receptor T-cell (CAR-T) therapy. $6+·V PHPEHUV DUH DW WKH IRUHIURQW RI WKLV WKHUDS\ FR treatment to patients with lymphoma and leukemia. Patients receiving CAR-T therapy are the sickest of the sick and have typically exhausted all other treatments, including chemotherapy, radiation, or stem cell transplant. This therapy represents a potentially life-saving option to patients whose care needs are currently unmet by existing therapeutics and who would otherwise receive high-cost, ineffective treatments.

The Society has been actively engaged on this issue, working closely with CMS, and other stakeholder groups, to share our thoughts a QG FRQFHUQV $6+·V PDLQ SULRULW\ LV SURWHFW to this potentially curative therapy. As of September 30, 2018, there have only been 348 CAR-T Medicare cases, and of that, at Prospective Payment System (PPS) hospitals, only 108 were non-clinical trial cases (Appendix

- Use the newly calculated cost as the starting point in the NTAP and outlier calculations.

Increasing the NTAP amount and operationalizing the CCR of 1.0 in this way - recognizing the CAR-T product acquisition cost, not the marked-up charge - provides numerous benefits to the institutions providing CAR-T, the patients in need of this therapy, as well as to CMS.

For institutions, it will eliminate the need for mark-up of the CAR-T product, ensuring that all institutions, regardless of their mark-up practices, are eligible to receive the full NTAP. The data available, included in Appendix C, shows that while many institutions are appropriately marking up the cost of the CAR-T product in order to access the full NTAP, there are also many institutions not appropriately marking up the charge, and therefore, not receiving the full NTAP that is available.

$GGLWLRQDOO\ LI &06 DFFHSWHG WKH $+$ UHTXHVW WR LQFUHDVH WKH 17$3 WR 80 SHUFHQW WKH DJHQF\ ZRXOG KDYH LQFUHDVHG WKH 17$3 DPRXQW WR $298,400 of the $373,000 product cost for all institutions. Institutions will still not be made whole on the acquisition cost, but this will help alleviate more of the financial burden faced when providing potentially curative therapies, such as CAR-7 $6+ DSSUHFLDWHV WKDW &06·V SURSRVDO for all eligible products; however, the Society, does not believe this proposal goes far enough to improve patient access to CAR-T and other new technologies. Even with the proposed increase to the NTAP amount for CAR-T, institutions will still be covering a significant portion of the product cost.

ASH first made the request to increase the NTAP cap to 80 percent in discussions with the agency earlier this \HDU DQG EHOLHYHV WKLV VXJJHVWLRQ LV D ORJLFDO RXWJURZWK centers delivering CAR-T as well as other NTAP-eligible products and services. Furthermore, AHA performed an analysis that showed that only 33 percent of NTAP dollars have been paid out since the NTAP was first implemented in 2001.[2] CMS has saved a significant sum on these payments that may offset the additional increase ASH is recommending.

ASH has heard anecdotally that institutions have been reluctant to make the investments necessary to run a CAR-T program knowing that under the best-case scenario, they will not be able to recuperate half of the SURGXFW·V FRVW IRU 0HGLFDUH SDWLHQWV 7R UHLWHUDWH

agency could add an edit between value code 86 and the CAR-T ICD-10-PCS procedure codes to give providers an opportunity to resubmit the claim when the value code is left incomplete.

Proposed FY 2020 Status of Technologies Approved for FY 2019 New Technology Add-on Payments

KYMRIAH® (Tisagenlecleucel) and YESCARTA® (Axicabtagene Ciloleucel)

ASH supports CMS continuing the NTAP for KYMRIAH® and YESCARTA® for all of FY 2020. ASH is currently analyzing Medicare claims data for CAR-T therapy. It is evident from our review that more data is needed before it would be appropriate to make further decisions toward rate-setting and/or developing alternative payment proposals. Expanding the NTAP for all of FY 2020 and requiring institutions to report value code 86 on inpatient claims, as outlined above, will help to allow continued data collection to inform future payment decisions.

CAR-T Reimbursement Recommendations for FY 2021 and Beyond

$6+ VXSSRUWV &06· SURSRVD-T cases to MS-DRG 016 in FY 2020. ASH cannot recommend the creation of a new MS-DRG at this time based on existing data, which includes a small number of CAR-T cases with inconsistent charges. ASH appreciates that the agency is considering different approaches for future rate setting for CAR-T and urges CMS to consider the suggestions belo

considering issues such as CAR-T. ASH has focused its IPPS rule comments on policies applicable to PPS institutions, but recognizes that PPS-exempt centers that operate under TEFRA are responsible for half of the CAR

Additionally, ASH has outlined its position regarding this important matter in its [Statement on Opioid Use in Patients with Hematologic Diseases and Disorders].

Sanofi NTAP Application for CABLIVI

$6+ VXSSRUWV WKH 6DQRIL &RPSDQ\·V 17$3 DSSOLFDWLRQ IR -year) for FY 2020. ASH subject matter experts were consulted and agree that using Cablivi for treatment of patients with acquired thrombotic thrombocytopenic purpura (aTTP) has the potential to save the lives of those individuals who do not respond to current conventional treatment, plasma exchange, corticosteroids, and rituximab. Cablivi differs from the treatments currently available for aTTP because it immediately prevents platelets from binding to the abnormally large von Willebrand factor molecules, a key abnormality of TTP. Without bound platelets, the thrombosis is prevented. Cablivi blocks the tissue injury, but corticosteroids, rituximab, and plasma exchange, are still needed to affect the cause of the disease.

Thank you for the opportunity to provide comments on the proposed rule for the Hospital Inpatient

Appendix A

Breakdown of Case Volume

31 of the cases were from October 1, 2017 to December 31, 2017

317 of the cases were from January 1, 2018 to September 30, 2018

*Comes from 107 cases

Append6 (e)-14 4 nMtn

PPS Hospital Pharmacy Charges

“*” = Numbers with counts of less than 11, or counts that could lead to a calculation of less than 11; all further breakdowns of the total number by clinical trial and nɵn clinical trial for volume would have met this criteria; therefore those breakdowns have not been shown

Appendix D