CMS Updates CAR-T Reimbursement for 2022 in IPPS Final Rule

Summary

Finalized policy for Medicare’s CAR-T inpatient reimbursement builds on policies solidified in last year’s rulemaking. Looking ahead, stakeholders will continue to weigh the appropriateness of payment.

In the fiscal year (FY) 2022 Inpatient Prospective Payment System (IPPS) final rule, the Centers for Medicare & Medicaid Services (CMS) finalized proposals to continue utilizing its newly established Medicare Severity Diagnosis-Related Group (MS-DRG) for CAR-T treatment stays, with differential reimbursement based on whether the product was provided as part of a clinical trial. However, the CMS will use 2019 spending data to establish the relative weight for the MS-DRG rather than using 2020 spending data, due to the impact of the COVID-19 pandemic on inpatient utilization patterns in 2020. Additionally, the CMS will add additional procedure codes affecting pre-Major Diagnosis Category MS-DRG 018 and will rename the MS-DRG to “Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies” to account for these changes. The financial impact of these changes will vary by hospital and in some cases may continue to fall short of fully recognizing provider costs of treatment. This policy will impact the way future inpatient cell-based immunotherapies are paid by Medicare, accounting for a broader suite of treatments.

Background
Since the first Food & Drug Administration (FDA) approval of a CAR-T product in 2017, concerns have persisted over how the Medicare program reimburses for these products, which are currently administered in the inpatient setting and have a significant cost for providers (e.g., $373,000 average sales price for 1 indication). Hospital inpatient reimbursement is calculated on an episodic basis using an MS-DRG base payment rate that is adjusted for factors such as hospital geography, new technology add-on payment (NTAP), and outlier payments.

In FY 2021, inpatient stays with CAR-T treatment are assigned to MS-DRG 018, which has an average national reimbursement rate of $239,933. Hospitals may receive additional payments for products with NTAP status; however, the NTAP is limited to 65% of the product cost, and no CAR-T products receive NTAP for FY 2021. Outlier payments are available to hospitals to cover extremely costly cases in which the costs of the case exceed the MS-DRG payment, NTAP payment (if applicable), and the fixed loss threshold of $29,064. Even with these adjustments, Medicare reimbursement for CAR-T cases today sometimes fails to cover total hospital costs, with potential negative impacts on provider uptake and patient access.

Finalized FY 2022 Changes

For FY 2022, the CMS finalized several policies that impact provider reimbursement for CAR-T:

- **Increase Payment for CAR-T Cases**: Due to an increase to the finalized base operating and capital rates for all IPPS payments as well as an increase in the relative weight for MS-DRG 018, the base payment for CAR-T cases in FY 2022 will increase by 2.9% to $246,958. This is slightly lower than the 3.2% increase in the proposed rule.

- **Rename and Broaden CAR-T MS-DRG**: The CMS finalized the action to rename MS-DRG 018 to “Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies” to reflect the addition of new procedure codes for non-CAR T-cell therapies and other immunotherapies that would map to the MS-DRG. Over time, this means more cases will be incorporated when setting reimbursement.

- **Use 2019 Data to Establish Payment**: The CMS finalized the use of 2019 Medicare Provider Analysis and Review (MedPAR) data to set relative weights for MS-DRGs, going against a standard process that would have incorporated 2020 MedPAR data for FY 2022. This change in method is due to the COVID-19 pandemic’s impact on utilization during 2020. In the case of CAR-T, this means that FY 2022 rates will be largely based on cost data incorporating the 2 on-market products that were available in 2019, despite additional products having been approved or used in clinical trials since.

- **Apply Adjustment to Clinical Trial Cases**: The CMS finalized a proposal to continue reimbursing for CAR-T clinical trial cases, which do not incur CAR-T drug costs, at a lower rate than non-clinical trial cases. The CMS will continue to utilize 2019 MedPAR data to determine the adjustment factor for FY 2022 clinical trial cases and, therefore, will continue using an adjustment factor of 0.17 for MS-DRG 018 cases. The base rate for clinical trial cases in FY 2022
will be $41,983.

- **Product NTAP Decisions**: In the proposed rule, the CMS evaluated 4 NTAP applications for CAR-T products. The CMS considered public comments on whether each product meets newness, cost, and clinical improvement criteria required for NTAP status in FY 2022 and made the following decisions:
  - NTAP approved for 2 CAR-T therapies:
    - Tecartus™ (brexucabtagene autoleucel) was approved for treatment of relapsed/refractory mantle cell lymphoma. The maximum NTAP payment will be $259,350.
    - Abecma® (idecabtagene vicleucel) was approved for treatment of relapsed/refractory multiple myeloma. The maximum NTAP payment will be $272,675.
  - NTAP denied for 1 CAR-T therapy:
    - Breyanzi® (lisocabtagene maraleucel), for treatment of relapsed/refractory large B-cell lymphoma, was denied NTAP due to failure to meet the newness and substantial clinical improvement criteria.
  - NTAP application withdrawn for 1 CAR-T therapy:
    - Ciltacabtagene autoleucel, for treatment of multiple myeloma, was withdrawn.

Figure 1. Hospital Reimbursement Example for CAR-T Cases Under IPPS, Final FY 2021 vs. Final FY 2022
Assumptions

- Hospital charges for CAR-T episode are kept constant across all examples, consistent with the geometric mean charges included in the FY22 Final Rule After Outliers Removed/Before Outliers Removed file ($1,408,774).
- Hospital has an average operating and capital cost-to-charge ratio (CCR) of 0.3.
- Hospital has an indirect medical education adjustment factor of 0.2 and disproportionate share hospital adjustment of 0.05.
- Hospital area wage index is 1.0.

Key Considerations Looking Ahead

Stakeholders should consider potential implications stemming from the finalized 2022 changes for existing assets and for future cell and gene therapies.

- Impact of MS-DRG 018 Expansion: The finalized FY 2022 base rate for MS-DRG 018 is generally in line with FY 2021. Total reimbursement will vary by hospital and case, with adequate reimbursement in some cases but with potential financial risk for hospitals on significantly costly cases. However, the inclusion of additional immunotherapies that could be mapped to MS-DRG 018 may lead to changes in the base rate over time. This could result in uniform reimbursement for cases that differ significantly in resource costs. Notably, the CMS did recognize in the final rule that hospitals could align charges for CAR-T products with CCRs and noted that a new cost center for CAR-T could be considered, which would likely increase payments over time if adopted.

- Availability of NTAP for CAR-T: It is beneficial to manufacturers that the CMS continues to recognize the newness and cost of CAR-T products despite soliciting comment on whether new CAR-Ts assigned to MS-DRG 018 should be ineligible for NTAP. The overall impact of NTAP on reimbursement will depend on how significantly costs of new products deviate from the costs of products currently incorporated into the MS-DRG calculation.

- Alternative Payment & Value-Based Arrangements: Last year, the CMS finalized the Medicaid Value-Based Purchasing final rule to establish flexibilities to implement value-based arrangements in the commercial and Medicaid markets, which could be attractive financing options for CAR-Ts. In the coming years, the CMS may consider whether innovative approaches should extend to the Medicare fee-for-service or Medicare Advantage space, potentially through a Center for Medicare & Medicaid Innovation demonstration.

- Potential for Shifts in Site of Care: As CAR-T treatment toxicity profiles increasingly make a move to outpatient sites of care more viable, providers may face different financial risk considerations. However, a shift in volume toward the outpatient setting could also result in increased scrutiny on Medicare payment in that setting, potentially resulting in changes to current reimbursement, which is average sale price plus 6 percent for separately payable drugs.

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