janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

May 2019

Q&A: Chimeric Antigen Receptor (CAR) T-Cell Therapy in the FY 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule

Comments due June 24, 2019

Background

On May 3, 2019, the Centers for Medicare and Medicaid Services (CMS) issued the fiscal year (FY) 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule. The CMS fact sheet is available here. In the FY 2020 IPPS Proposed Rule, CMS addresses how the agency proposes to pay for CAR T-cell therapy administered on an inpatient basis.

Q. What are the key policies that CMS addressed relating to reimbursement for CAR T-cell therapies?

A. In the Proposed Rule, CMS:

- proposed to maintain the ICD-10 codes for CAR T-cell therapy (i.e., codes XW033C3 and XW043C3), as part of an existing DRG for Bone Marrow Transplants (MS-DRG 16 - Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy), which continues to amount to a fraction of the cost of the therapy;
- proposed to increase the maximum New Technology Add-On Payment (NTAP) amount. Currently, the NTAP is the lesser of: (1) 50% of the average cost of the technology; or (2) 50% of the costs in excess of the MS-DRG payment. CMS proposed to increase the payment percentage in each category to 65%;
- proposed to continue NTAPs for Kymriah™ and Yescarta™;
- requested comments regarding payment methodology alternatives in general and on specific alternative approaches, such as:
    - creating a new DRG with its own associated adjustments, exceptions, and relative weight;
    - using a specific cost-to-charge ratio (CCR) for CAR T-cell therapy, such as 1.0, when determining outlier payments, NTAPs, and payments to IPPS-excluded cancer hospitals;
    - eliminating use of CCRs in calculating NTAPs and instead making a uniform add-on payment equal to the proposed maximum NTAP; or

- using a higher percentage than the proposed 65% to calculate the maximum NTAP amount;

- sought comments on proposals regarding ways to demonstrate, for purposes of the NTAP application, that a service or technology is a "substantial clinical improvement" over existing services or technologies; and

- requested comments on how its payment decisions may affect:

  - access to care;

  - incentives to lower drug costs; and

  - CMS efforts to encourage value-based care.

This Q&A document provides an overview of the implications of the Proposed Rule for CAR T-cell therapy and identifies key areas for potential comments.

I. Current Payment Framework and Existing Payment Adjustments

Q. How does CMS pay for CAR T-cell therapies under the current payment framework?

A. CMS pays for CAR T-cell therapies based on the DRG to which they are assigned, MS-DRG 16 - Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy. Reimbursement under this DRG is significantly less than the list price of each of the two approved CAR T-cell therapies.[1]

Q. Are hospitals reimbursed under the prospective payment system (PPS) currently eligible to receive any additional payments for CAR T-cell therapies?

A. Hospitals reimbursed under the PPS are eligible to receive two types of additional payments:

- "outlier payments" provided in addition to the basic prospective payments for cases incurring extraordinarily high costs; and

- NTAPs, which CMS may assign to qualifying breakthrough technologies.

However, the outlier payments and NTAPs, even if approved by CMS, do not fully account for the high costs of CAR T-cell therapy products.

[1] *See* Letter from Am. Soc'y for Blood and Marrow Transplantation to the CMS, *Follow-up to August 30, 2018 Meeting; Proposed CART-T Coverage and Payment Options* (Nov. 1, 2018), at 2.

Q. Why are outlier payments currently insufficient to account for the costs of CAR T-cell therapies?

A. Outlier payments cover 80% of costs above the DRG amount plus an established threshold amount.[2] However, to estimate costs to be used in the outlier payment calculation, CMS multiplies the hospital's charges by a hospital-specific CCR.[3] For example, to recoup close to the full cost of the drug, a hospital with a 0.25 CCR would be forced to mark up the charge by about 400% for the payment to approximate the drug cost.[4] Hospitals have stated, and CMS has acknowledged, that hospitals are unlikely to make such a markup because it would create significant complications for patients and could be challenged by their local Medicare Administrative Contractors (MACs).[5]

[2] *See* CMS, Medicare Claims Processing Manual, Pub. No. 100-04, Ch. 3, § 20.1.2.

[3] *Id.*

[4] See Am. Soc'y for Blood and Marrow Transplantation, *CMS Super Session: CAR-T & Cellular Therapy Coverage, Coding, Reimbursement & Policy Updates* (Feb. 22, 2019), https://higherlogicdownload.s3.amazonaws.com/ASBMT/43a1f41f-55cb-4c97-9e78-c03e867db505/UploadedImages/TCT_CAR-T_Final_Presentation_for_Friday_Feb_22_2019.pdf at 24-28.

[5] Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates, 84 Fed. Reg. 19,158, 19,182 (May 3, 2019) [hereinafter Proposed Rule]; *see also* Letter from Am. Soc'y for Blood and Marrow Transplantation to the CMS, *CMS Payment Models for Chimeric Antigen Receptor T Cell (CAR-T) Therapy* (Sept. 6, 2017), https://higherlogicdownload.s3.amazonaws.com/ASBMT/UploadedImages/6cfeff77-6acc-46fe-8d3d-db9dddebe47a/ASBMT_Letter_CMS_CAR_T_9_6_17_Final.pdf at 10.

Q. Why are NTAPs currently insufficient to account for the costs of CAR T-cell therapies?

A. Currently, there are NTAPs for the two FDA-approved CAR T-cell therapies, Kymriah™ and Yescarta™. Similar to outlier payments, to estimate costs to be used in the NTAP payment calculation, CMS multiplies the hospital's charges by a hospital-specific CCR. Additionally, NTAPs are currently calculated such that the NTAP only covers up to 50% of the cost of a given therapy.[6] As a result, a significant mark-up would be required for payment to approximate drug cost.

Q. How are PPS-exempt cancer hospitals paid for CAR T-cell therapies?

A. The cost of the CAR T-cell therapies far exceed Medicare payment for PPS-exempt cancer hospitals as well.[7] PPS-exempt cancer centers are reimbursed for their actual costs, but these costs are limited by a cap based on costs of previous years, which do not reflect these expensive new treatments.[8] PPS-exempt cancer hospitals are eligible for relief payments that cover 50% of costs greater than 110% of their cap, up to a total additional reimbursement of 10% of their cap. However, these relief payments provide less than half of the costs of the drug.[9] PPS-exempt hospitals may also file exception requests to receive additional reimbursement if new treatments increase costs; although these appeals often take over a decade to be resolved and thus would not provide timely reimbursement for these therapies.[10]

II. Overview of CAR T-Cell Therapy Payment Options

Q. How did CMS propose to address payment for CAR T-cell therapy?

A. CMS proposed to maintain its prior assignment of the ICD-10 codes for CAR T-cell therapy (i.e., codes XW033C3 and XW043C3) to a DRG for bone marrow transplants (MS-DRG 16 - Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy).[11] CMS had considered other existing MS-DRGs as well.[12] For

---

[6] *See* 42 C.F.R. § 412.88.

[7] A list of the PPS-exempt cancer hospitals is available here. CMS, PPS-Exempt Cancer Hospitals (PCHs) (Dec. 7, 2017), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/PPS_Exc_Cancer_Hospasp.html.

[8] *See* 42 U.S.C. § 1395ww(b)(1).

[9] *See* 42 U.S.C. § 1395ww(b)(1)(C).

[10] *See* 42 U.S.C. § 1395ww(b)(4)(A)(i); 42 C.F.R. § 413.40(g)(3).

[11] Proposed Rule at 19,180-81.

[12] *See* Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates, 83 Fed. Reg. 20,164, 20,189 (May 7, 2018).

example, some stakeholders identified the MS-DRGs associated with treatment of leukemia and lymphoma for assignment, which pay a base reimbursement ranging from approximately $6,000 to $19,000.[13] In contrast, the MS-DRG 16 pays a base reimbursement of approximately $40,000. However, the reimbursement associated with this DRG is still less than one-ninth of the estimated average cost for an administered dose of the approved CAR T-cell therapies.

CMS also proposed to continue NTAPs for Kymriah™ and Yescarta™.[14] Note that, as proposed, this payment would continue to vary considerably based on hospital-specific CCRs.

Q. Did CMS mention other options to address payment for CAR T-cell therapy?

A. Yes. CMS also discussed a number of other alternatives and requested comment on how best to pay for CAR T-cell therapies. These included: (1) creating a new DRG for CAR T-cell therapy;[15] and (2) using a CCR of 1.0 to determine outlier payments, NTAPs, and PPS-exempt cancer center payments, which could be implemented in a way that essentially pays providers for the cost of acquiring the drug.[16]

III. DRGs

Q. How does the assignment of multiple CAR T-cell therapies to one DRG affect payment?

A. DRG relative weights are multiplied by hospital-specific factors to determine reimbursement for inpatient care in PPS hospitals. These DRG relative weights are ordinarily based on average charges from previous years. To the extent the charges associated with CAR T-cell therapies generally reduce over time, the DRG relative weight would also likely decrease, affecting payment for each therapy in the DRG.

[13] *See* CMS, FY 2020 IPPS Proposed Rule Tables tbls. 1A, 5, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Proposed-Rule-Home-Page-Items/FY2020-IPPS-Proposed-Rule-Tables.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending (last visited May 3, 2019); *see also* Letter from Am. Soc'y for Blood and Marrow Transplantation to the CMS, *Request for New MS-DRGs for CAR-T Therapy for FY 2019* (Nov. 1, 2017), https://higherlogicdownload.s3.amazonaws.com/ASBMT/43a1f41f-55cb-4c97-9e78-c03e867db505/UploadedImages/ASBMT_Request__FY2019_New_CAR-T_MS-DRGs_.pdf, at 5.

[14] Proposed Rule at 19,278-79.

[15] *Id.* at 19,180-81.

[16] *Id.* at 19,182.

Q. How would the establishment of a new DRG for CAR T-cell therapy affect payment?

A. The creation of a new DRG for CAR T-cell therapy could potentially provide sufficient payment for PPS hospitals depending on how CMS decided to set the DRG weight. However, CMS has stated it does not currently have the comprehensive clinical and cost data needed to determine a relative weight for a new DRG.[17]

Q. Did CMS discuss how it could set the relative weight for a new MS-DRG for CAR T-cell therapy?

A. Yes. CMS discussed two options for setting relative weight and requested comment regarding: (1) dividing the average costs of cases that include the CAR T-cell procedures by the average costs of all cases; and (2) using an "appropriate portion" of the average sales price (ASP) for CAR T-cell therapies.[18]

IV. NTAPs

Q. What are the criteria to qualify for the NTAP?

A. To qualify for an NTAP, a service or technology must:

1) substantially improve, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries;

2) be sufficiently new; and

3) not be reimbursed sufficiently in the existing DRG system.[19]

Q. How did CMS propose to modify NTAPs to reflect the costs of new technologies more accurately?

A. Currently, the NTAP is the lesser of: (1) 50% of the average cost of the technology; or (2) 50% of the costs in excess of the MS-DRG payment.[20] CMS proposed to increase the payment percentage in each category to 65%. If adopted, the maximum NTAP amount for Kymriah™ and Yescarta™ would increase from $186,500 to $242,450.[21]

Q. How did CMS propose to address previously approved NTAPs for Kymriah™ and Yescarta™?

---

[17] *Id.* at 19,181.

[18] *Id.*

[19] *See* 42 C.F.R. § 412.87(b).

[20] 42 C.F.R. § 412.88(a)(2); Proposed Rule at 19,373.

[21] Proposed Rule at 19,279.

A. CMS proposed to continue to apply NTAPs for the two FDA-approved CAR T-cell therapies because they continue to meet the NTAP requirements.[22] Last year, CMS made a single NTAP determination that applied to both therapies.[23] CMS proposed to maintain its FY 2019 single add-on evaluation determination for the two approved CAR T-cell therapies, because they are "intended to treat the same or similar disease in the same or similar patient population, and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action."[24]

Q. What is the significance of considering the NTAP applications for Kymriah™ and Yescarta™ together?

A. For purposes of determining payment for these two drugs in FY 2020, considering them together appears to be of little consequence. However, CMS has applied the earliest market availability date submitted as the beginning of the NTAP newness period for both approved CAR T-cell therapies, which may limit otherwise available NTAP payments in a future year for the drug with later market availability.

CMS has made other NTAP decisions that apply to multiple similar therapies in the past. Moreover, NTAP reimbursement is based on actual charges for the technology, so grouping the two together would not impact reimbursement to providers.[25]

Nonetheless, the decision to consider the two NTAP applications together has potential longer-term implications. Combining the NTAP applications for these two therapies created precedent that may make it unlikely for future CAR T-cell therapies to be considered distinct from existing CAR T-cell therapies, or sufficiently new. As a result, CMS's continued combined decision for Kymriah™ and Yescarta™ makes it more likely that future CAR T-cell therapies may not qualify for NTAPs.

V. CCRs

Q. What is a CCR?

A. A CCR is the ratio of a hospital's cost (based on the hospital's financial cost report) and charges on claims. CMS uses CCR data to evaluate DRG weighting and to determine outlier payments. CCRs are used to discount

[22] *Id.* at 19,279.

[23] *Id.* at 19,278.

[24] *Id.*

[25] *See* 42 C.F.R. § 412.88(a)(2).

the charges a hospital lists for a particular service to arrive at the estimated cost of that service. Usually, CCRs are less than 1.0; for example, the median FY 2019 IPPS statewide average operating CCR is 0.268.[26]

Q. Did CMS discuss the use of a CCR to address payment for CAR T-cell therapy?

A. Yes. Although CMS did not formally propose this solution, CMS requested comment on reimbursing CAR T-cell therapy at a CCR of 1.0, which could be implemented in a way that essentially pays providers for the cost of acquiring the drug. Because of the extremely high cost of CAR T-cell therapy products and the complications associated with marking them up, a CCR of 1.0 would likely be an effective way of estimating the cost of these products. Depending on the context in which the CCR of 1.0 is applied, this could increase payment to providers by reimbursing them for the cost of acquiring the drug. It is unclear whether CMS would specify how costs are determined and reported to ensure that providers do not mark up the cost of the drug.

Additionally, CMS requested comment on a potential payment alternative that would eliminate the use of the CCR in calculating NTAPs for Kymriah™ and Yescarta™, and instead make a uniform add-on payment that equals the proposed maximum add-on payment.[27]

VI. Assessment of Potential Options

Q. Which options are likely to best support access to, and provision of, CAR T-cell therapy?

A. In short, CMS's proposal to continue assigning ICD-10 procedure codes for providing CAR T-cell therapy to MS-DRG 16 would not reimburse PPS hospitals for the full cost of the CAR T-cell therapy product; even with CMS's proposed continuation of NTAPs for Kymriah™ and Yescarta™, let alone the costs of providing follow up care. Moreover, this proposal provides no assistance to PPS-exempt cancer hospitals.

Creating a new DRG could support greater access to CAR T-cell therapy, though again this solution provides no assistance to PPS-exempt cancer hospitals, and would require reductions in payments for other services because DRG changes must be budget neutral.[28]

---

[26] This operating CCR is the median among acute care hospitals in urban areas. *See* CMS, FY 2019 IPPS Final Rule Tables tbl. 8A, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Final-Rule-Home-Page-Items/FY2019-IPPS-Final-Rule-Tables.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending (last visited May 3, 2019).

[27] *Id.*

[28] *See* 42 U.S.C. § 1395ww(d)(2)(F).

CMS also mentioned taking an "appropriate portion" of the ASP into account in developing a relative weight.[29] MedPAC has recommended that CMS use ASP in place of CCRs for NTAPs, outlier payments, and PPS-exempt cancer hospitals, which would more closely approximate payment in the outpatient setting.[30] Ultimately, either the creation of a new DRG that adequately covers the cost of providing the CAR T-cell therapy, or some mechanism that uses the CCR of 1.0 approach to provide payment for the cost of the CAR T-cell therapy to providers would provide the best access to CAR T-cell therapy.

Q. Is CMS willing to consider other ideas?

A. As discussed above, CMS proposed continuing its existing payment methodology (i.e., the assignment of CAR T-cell ICD-10 procedure codes to MS-DRG 16), but listed a number of other alternative proposals, and asked for general feedback on how to best respond to this issue. Specifically, CMS requested comment on how its decisions may affect: (1) access to care; (2) incentives to lower drug costs; and (3) CMS efforts to encourage value-based care.[31] CMS also requested comments on how the effective dates of any potential payment methodology alternatives, if adopted, may intersect, and affect future participation in the alternative approaches.[32] Taken together, these requests for comments seem to suggest that CMS is open to other alternatives.

VII. Outpatient Services Treated as Inpatient Services

Q. If a patient received their CAR T-cell therapy in the outpatient setting, under what circumstances could that service be changed into an inpatient service?

A. Outpatient care provided in the three calendar days before the date of an inpatient admission, or one calendar day in the case of PPS-exempt hospitals, is considered inpatient care if such outpatient care is related to the inpatient admission.[33] CMS considers a new day to begin at midnight. If a patient receives CAR T-cell therapy in an outpatient setting and is admitted to the hospital within the relevant time period, their care would be included in, and reimbursed as, an inpatient cost.

---

[29] Proposed Rule at 19,181.

[30] Letter from Medicare Payment Advisory Comm'n to the CMS, *File code CMS-1694-P* (June 22, 2018), http://www.medpac.gov/docs/default-source/publications/06222018_medpac_2019_ipps_comment_sec.pdf?sfvrsn=0.

[31] *See* Proposed Rule at 19,181.

[32] *See id*.

[33] *See* 42 U.S.C. § 1395ww(a)(4); 42 C.F.R. § 412.2(c)(5).

VIII. Commenting on the Proposed Rule

Q. How can an interested individual or organization submit comments on the Proposed Rule?

A. Interested stakeholders should submit comments electronically by visiting https://www.regulations.gov/document?D=CMS-2019-0073-0003. Refer to CMS-1716-P for comments on the Proposed Rule. Alternatively, comments can be submitted by mail at the following addresses:

Regular Mail
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1716-P
P.O. Box 8013
Baltimore, MD 21244-1850

Express or Overnight Mail
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1716-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

The deadline for submitting comments is 5:00 p.m. EDT on **June 24, 2019**.