Key Takeaways: FY 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule

Chimeric Antigen Receptor (CAR) T-Cell Therapy and Hospital Market-Based Data Reporting

Comments due June 28, 2021

On April 27, 2021, the Centers for Medicare and Medicaid Services (CMS) released the fiscal year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule.[1] The CMS fact sheet is available here. In the FY 2022 IPPS Proposed Rule, CMS addresses how the agency proposes to pay for CAR T-cell therapy administered on an inpatient basis. The agency also proposes to repeal certain hospital market-based data reporting requirements. Key takeaways regarding these aspects of the FY 2022 IPPS Proposed Rule are summarized below.

CAR T-Cell Therapy

- **CMS proposes to revise MS-DRG 18's title from "Chimeric Antigen Receptor (CAR) T-cell Immunotherapy" to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies."[2]**
  - **Current policy:** MS-DRG 18 is specifically for cases involving CAR T-cell therapy, and is currently assigned two related ICD-10-PCS codes (i.e., codes XW033C3 and XW043C3).[3] MS-DRG 18 currently pays base reimbursement of approximately $239,932.89.[4]
  - **Proposed change:** CMS would expand MS-DRG 18 to reflect the proposed inclusion of cases involving non-CAR T-cell therapies and other immunotherapies, in addition to CAR T-cell therapies.[5] CMS would add 16 new ICD-10-PCS codes for these therapies to MS-DRG 18.[6] MS-DRG 18 would pay a base reimbursement of approximately $247,583.82 in FY 2022.[7]
  - **Why it matters:** If adopted, the DRG's relative weight in future years would be calculated based on non-CAR T-cell therapies and other immunotherapies claims that group to MS-DRG 18, in addition to CAR T-cell therapy claims.[8]
- For FY 2022, CMS proposes to continue excluding clinical trial claims that group to MS-DRG 18 for purposes of calculating the DRG's relative weight so the DRG's relative weight will accurately reflect the cost of CAR T-cell therapy drugs.[9] CMS also proposes to maintain its payment adjustment methodology for clinical trial cases under MS-DRG 18, given the proposed exclusion from the DRG's relative weight.[10]
  - When a CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, CMS would continue to include the claim when calculating the average cost for MS–DRG 18 because the CAR T-cell therapy is not the product subject to the clinical trial.[11] The payment adjustment would not be applied in calculating the payment for the case.[12]
  - When there is expanded access use of immunotherapy, CMS would continue excluding these cases when calculating the average cost for MS–DRG 18.[13] The payment adjustment would be applied in calculating the payment of the case.[14]

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- **CMS proposes to use FY 2019 MedPAR claims data for FY 2022 ratesetting related to MS-DRG-18.**[15]
    - **Current policy:** FY 2020 MedPAR claims data would ordinarily be used for FY 2022 ratesetting, including the payment adjustor for MS-DRG-18.[16]
    - **Proposed change:** CMS proposes to continue to calculate the MS-DRG-18 payment adjustor based on the FY 2019 MedPAR file (previously used for the FY 2021 final rule) for purposes of establishing the FY 2022 payment amount.[17]
    - **Why it matters:** CMS explains that FY 2020 MedPAR claims data captures changes in inpatient hospital utilization driven by the COVID-19 public health emergency and that the use of FY 2019 MedPAR claims data would approximate expected FY 2022 inpatient hospital utilization.[18]
        - Under this proposal, CMS would continue to apply an adjustor of 0.17 to the applicable clinical trial cases.[19]
        - Based on an alternative approach using the FY 2020 data, CMS calculates a payment adjustor of 0.25 for applicable clinical trial cases that group to MS-DRG 18.[20] CMS requests comments on this alternative approach.[21]

Payment Components	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022 (Proposed)
DRG Base Reimbursement	No Specific CMS-Assigned MS-DRG[22]	$40K (Autologous Bone Marrow Transplant MS-DRG 16)[23]	$43K (Autologous Bone Marrow Transplant MS-DRG 16)[24]	$239K (CAR-T MS-DRG 18)[25]	$247K (CAR-T and Other Immunotherapies MS-DRG 18)[26]
Maximum New Technology Add-On Payment (NTAP) Amount	No NTAP[27]	50% of 373K, or $186.5K[28]	65% of $373K or $242.5K[29]	NTAPs for Current CAR-T Therapies Discontinued[30]	NTAP Applications for New CAR-T Therapies Under CMS Review[31]

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- **CMS solicits comments on NTAP applications for four CAR T-cell therapies, Breyanzi®, ABECMA®, Tecartus™, and Janssen's ciltacabtagene autoleucel (cilta-cel).[32]**

  - **Current policy:** CMS discontinued NTAPs for two FDA approved CAR T-cell therapies, Kymriah™ and Yescarta™, in FY 2021.[33] To qualify for 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 adequately in the existing DRG system.[34]

  - **Proposed change:** CMS outlines agency observations and concerns regarding whether Breyanzi®, ABECMA®, Tecartus™, and cilta-cel meet NTAP requirements for substantial clinical improvement, newness, and cost.[35]

  - **Why it matters:** If approved, the maximum NTAP would be the lesser of: (1) 65% of the average cost of the technology; or (2) 65% of the costs in excess of the MS-DRG payment.[36]

<u>**Hospital Market-Based Data Reporting Requirements**</u>

- **CMS proposes to repeal certain market-based data reporting requirements for hospitals.[37]**

  - **Current policy:** Under the FY 2021 IPPS Final Rule, CMS adopted a requirement for hospitals to include in their Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organization payers, by MS-DRG, for cost reporting periods ending on or after January 1, 2021.[38]

    Under the FY 2021 IPPS Final Rule, CMS also adopted a change of methodology for calculating MS-DRG relative weights to incorporate market-based rate information beginning in FY 2024.[39] This alternative methodology would have replaced the current use of gross charges as reflected in hospital chargemasters and cost information from Medicare cost reports to develop MS-DRG relative weights.[40]

  - **Proposed policy:** CMS proposes to repeal requirements for hospitals to report this market-based payment information on their Medicare cost report, which CMS would have used to incorporate market-based pricing into the methodology for calculating MS-DRG relative weights.[41]

    CMS also proposes to repeal the change of methodology for calculating MS-DRG relative weights to incorporate market-based rate information beginning in FY 2024.[42]

  - **Why it matters:** If adopted, hospitals would not be required to include this information on their Medicare cost report.[43] CMS solicits comments regarding this proposal.[44]

    Under the Proposed Rule, CMS would continue using the existing cost-based methodology for calculating the MS-DRG relative weights for FY 2024 and subsequent fiscal years.[45] The agency requests comment on this proposal.[46]

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Proposed Rule Comment Period

Interested stakeholders should submit comments electronically by visiting regulations.gov. 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-1752-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-1752-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments must refer to CMS-1752-P. The deadline for submitting comments is 5:00 p.m. EDT on **June 28, 2021**.

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[1] CMS, Medicare Program; 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 2022 Rates, Proposed Rule, 86 Fed. Reg. 25,070, *available at* https://www.govinfo.gov/content/pkg/FR-2021-05-10/pdf/2021-08888.pdf [hereinafter "IPPS Proposed Rule"].

[2] *Id.* at 25,095.

[3] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Final Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals; Final Rule, 85 Fed. Reg. 58,432, 58,451-53. (Sept. 18, 2020).

[4] *See* CMS, FY 2021 IPPS Final Rule: Correction Notice Tables tbls. 1A, 1D, 5, https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-final-rule-home-page#Tables (last visited May 7, 2021).

[5] IPPS Proposed Rule at 25,094–95.

[6] *Id.* at 25,095.

[7] *See* CMS, FY 2022 IPPS Proposed Rule Tables tbls. 1A, 1D, 5, https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-proposed-rule-home-page#Tables (last visited May 7, 2021).

[8] *See, e.g.*, 85 Fed. Reg. 58,509 ("Each year, we calculate the relative weights by dividing the average cost for cases within each MS–DRG by the average cost for cases across all MS–DRGs. It is to be expected that when MS–DRGs are restructured, resulting in a different case-mix within the new MS–DRGs, the relative weights of the MS–DRGs will change as a result.").

[9] IPPS Proposed Rule at 25,201.

[10] *Id.* at 25,528; *see* 42 C.F.R. § 412.85(c); *id.* § 412.312.

[11] IPPS Proposed Rule at 25,201.

[12] *Id.* at 25,528.

[13] *Id.*

[14] *Id.*

[15] *Id.* at 25,201.

[16] *Id.* at 25,201-02.

[17] *Id.* at 25,201.

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[18] CMS, Fact Sheet; Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) Rates Proposed Rule (CMS-1752-P) (Apr. 27, 2021), https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2022-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care.

[19] IPPS Proposed Rule at 25,528.

[20] *Id.*

[21] *Id.* at 25,201–02.

[22] 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 at 7 (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.

[23] *See* CMS, FY 2019 IPPS Final Rule: Correction Notice Tables tbls. 1A, 1D, 5, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Final-Rule-Home-Page-Items/FY2019-IPPS-Final-Rule-Tables (last visited May 7, 2021).

[24] *See* CMS, FY 2020 IPPS Final Rule: Correction Notice Tables tbls. 1A, 1D, 5, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Tables (last visited May 7, 2021).

[25] *See* CMS, FY 2021 IPPS Final Rule tbls. IA, ID, 5, https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-final-rule-home-page#Tables (last visited May 7, 2021).

[26] CMS, FY 2022 IPPS Proposed Rule Tables tbls. 1A, 1D, 5, https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-proposed-rule-home-page#Tables (last visited May 7, 2021).

[27] *See* Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices, 82 Fed. Reg. 37,990, 38,115 (Aug. 14, 2017).

[28] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims; Final Rule, 83 Fed. Reg. 41,144, 41,299 (Aug. 17, 2018).

[29] Medicare Program; 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; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals; Final Rule, 84 Fed. Reg. 42,044, 42,187 (Aug. 16, 2019).

[30] 85 Fed. Reg. 58,611.

[31] *See* IPPS Proposed Rule at 25,227–39, 25,256–61, 25,329–39.

[32] *Id.*

[33] 85 Fed. Reg. 58,611.

[34] *See* 42 C.F.R. § 412.87(b)(1)–(3).

[35] IPPS Proposed Rule at 25,227–39, 25,256–61, 25,329–39.

[36] 42 C.F.R. § 412.88(a)(2)(ii).

[37] IPPS Proposed Rule at 25,527.

[38] 85 Fed. Reg. 58,881.

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[39] *Id.*

[40] *Id.* at 58,873–75.

[41] IPPS Proposed Rule at 25,527.

[42] *Id.*

[43] *Id.*

[44] *Id.* at 25,527–28.

[45] *Id.* at 25,527.

[46] *Id.* at 25,528.

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