

Key Takeaways: FY 2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule

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

Comments due July 10, 2020

On May 29, 2020, the Centers for Medicare and Medicaid Services (CMS) published the fiscal year (FY) 2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) [Proposed Rule](#).¹ The CMS fact sheet is available [here](#). In the FY 2021 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 implement certain hospital market-based data reporting requirements. Key takeaways regarding these aspects of the FY 2021 IPPS Proposed Rule are summarized below.

CAR T-Cell Therapy

- **CMS proposes to create a new MS-DRG (MS-DRG 18 - Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) specifically for cases involving CAR T-cell therapy, using available clinical and cost data.**²
 - The proposed MS-DRG 18 would pay a base reimbursement of approximately \$239,490.17 compared to the current bone marrow transplant DRG used for cases involving CAR T-cell therapy, which currently pays a base reimbursement of approximately \$43,094.19.³
 - CMS would reassign the ICD-10 codes for CAR T-cell therapy (i.e., codes XW033C3 and XW043C3) from an existing MS-DRG for bone marrow transplants (MS-DRG 16 - Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy) to the new CAR T-cell therapy DRG.⁴
 - Any future ICD-10 codes for CAR T-cell therapies would be added to the most appropriate MS-DRG, as determined by CMS.⁵
 - CMS proposes to exclude clinical trial claims that group to the new CAR T-cell therapy MS-DRG for purposes of calculating the DRG's relative weight so the DRG's relative weight will reflect the cost of CAR T-cell therapy drugs. CMS requests comments regarding this proposal.⁶
 - For clinical trial cases, in which the provider typically does not incur the cost of the drug, CMS proposes a payment adjustment under the new CAR T-cell therapy MS-DRG, as the DRG's relative weight would exclude clinical trial cases.⁷ CMS solicits comments on this proposal.⁸

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Payment Components	FY 2018	FY 2019	FY 2020	FY 2021 (Proposed Rule)
DRG Base Reimbursement	No Specific CMS-Assigned MS-DRG ⁹	\$40K (Autologous Bone Marrow Transplant MS-DRG 16) ¹⁰	\$43K (Autologous Bone Marrow Transplant MS-DRG 16) ¹¹	\$239K (CAR-T MS-DRG 18) ¹²
Maximum New Technology Add-On Payment (NTAP) Amount	No NTAP ¹³	50% of 373K, or \$186.5K ¹⁴	65% of \$373K or \$242.5K ¹⁵	NTAPs for Current CAR-T Therapies Discontinued ¹⁶

- **CMS proposes to increase the NTAP cost threshold for CAR T-cell therapies to \$1,237,393.¹⁷**
 - 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
 3. not be reimbursed adequately in the existing DRG system.¹⁸
 - As to the third criterion, CMS evaluates the adequacy of available reimbursement based on the application of an MS-DRG cost threshold. Currently, CMS uses the applicable cost threshold in effect when an NTAP application is submitted to conduct this evaluation.¹⁹
 - CMS sets the NTAP cost threshold for each DRG by taking the geometric mean standardized charge for all cases in the DRG and adding the lesser of:
 - 75% of the standardized payment amount (increased to reflect the difference between cost and charges),²⁰ or
 - 75% of one standard deviation of mean charges by MS-DRG.²¹
 - CMS proposes to apply the new CAR T-cell therapy DRG's cost threshold (\$1,237,393) to previously approved CAR T-cell therapies and to new CAR T-cell therapy NTAP applicants for FY 2021.²² The current cost threshold (under MS-DRG 16) is \$170,573.²³
 - CMS proposes to expand this NTAP cost threshold policy to all other non-CAR T-cell therapy technologies in FY 2022.²⁴
 - CMS solicits comments regarding these proposals.²⁵

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- **CMS proposes to discontinue NTAPs for Kymriah™ and Yescarta™ in FY 2021 pursuant to the standard newness requirement.**²⁶
 - Based on the entry date of this technology onto the U.S. market, CMS finds that these two FDA-approved CAR T-cell therapies will no longer meet the NTAP requirement for newness in FY 2021.²⁷ Additionally, CMS finds that Kymriah™ and Yescarta™ will not meet the NTAP cost threshold requirement in FY 2021 under the new CAR T-cell therapy DRG's cost threshold.²⁸
- **CMS solicits comments on NTAP applications for two CAR T-cell therapies, KTE-X19 and Liso-Cel™.**²⁹ The agency outlines its concerns regarding whether these drugs meet NTAP requirements for substantial clinical improvement, newness, and cost.³⁰

Hospital Market-Based Data Reporting Requirements

- **CMS proposes to require hospitals to report certain market-based payment information on their Medicare cost report, which CMS would use to incorporate market-based pricing into the methodology for calculating MS-DRG relative weights.**³¹
 - Under the Proposed Rule, hospitals would be required to include the following information on the Medicare cost report:
 - Median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organization payers, by MS-DRG, and
 - Median payer-specific negotiated charge that the hospital has negotiated with all of its third-party payers, including MA organizations, by MS-DRG.³²
 - CMS explains that hospitals would use the payer-specific negotiated charge data that they will be required to make public under the agency's new regulations regarding hospital price transparency, which take effect January 1, 2021, to calculate these medians.³³
 - The agency solicits comment on this proposal. In particular, CMS requests comment on any alternative data collection requirements that would capture market-based information, including median negotiated reimbursement amount.³⁴
- **CMS proposes to change the methodology for calculating MS-DRG relative weights to incorporate this market-based rate information beginning in FY 2024.** This alternative methodology would replace the current use of gross charges as reflected in hospital chargemasters and cost information from Medicare cost reports to develop MS-DRG relative weights.³⁵
 - Under the Proposed Rule, CMS would use the median payer-specific negotiated charge for each MS-DRG for payers that are MA organizations as part of the relative weight calculation. The agency sets forth a proposed methodology and requests comment.³⁶

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Proposed Rule Comment Period

Interested stakeholders can submit comments electronically by visiting [regulations.gov](https://www.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-1735-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-1735-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments must refer to CMS-1735-P. The deadline for submitting comments is 5:00 p.m. EDT on **July 10, 2020**.

¹ 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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals, 85 Fed. Reg. 32,460 (May 29, 2020), *available at* <https://www.govinfo.gov/content/pkg/FR-2020-05-29/pdf/2020-10122.pdf> [hereinafter “Proposed Rule”].

² *Id.* at 32,475-76.

³ See CMS, FY 2021 IPPS Proposed Rule Tables tbls. 1A, 1D, 5, <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipp-proposed-rule-home-page#Tables> (last visited June 4, 2020); CMS, FY 2020 IPPS Final Rule: Correction Notice Tables tbls. 1A, 1D, 5, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcutelnpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Tables> (last visited June 4, 2020).

⁴ Proposed Rule at 32,476.

⁵ *Id.*

⁶ *Id.* at 32,566.

⁷ *Id.* at 32,764-65.

⁸ *Id.* at 32,765.

⁹ 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.

¹⁰ See CMS, FY 2019 IPPS Final Rule: Correction Notice Tables tbls. 1A, 1D, 5, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcutelnpatientPPS/FY2019-IPPS-Final-Rule-Home-Page-Items/FY2019-IPPS-Final-Rule-Tables> (last visited June 4, 2020).

¹¹ See CMS, FY 2020 IPPS Final Rule: Correction Notice Tables tbls. 1A, 1D, 5, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcutelnpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Tables> (last visited June 4, 2020).

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¹² See CMS, FY 2021 IPPS Proposed Rule Tables tbls. 1A, 1D, 5, <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipp-pps-proposed-rule-home-page#Tables> (last visited June 4, 2020);

¹³ 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).

¹⁴ 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).

¹⁵ 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).

¹⁶ Proposed Rule at 32,573-74.

¹⁷ *Id.* at 32,573.

¹⁸ See 42 C.F.R. § 412.87(b)(1)-(3).

¹⁹ Proposed Rule at 32,643.

²⁰ See CMS, FY 2021 IPPS Proposed Rule Home Page, FY 2021 IPPS Proposed Rule Data Files, FY 2022 New Technology Thresholds Proposed Rule, FN 1, <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipp-pps-proposed-rule-home-page#DataFiles> (last visited June 4, 2020); 42 C.F.R. § 412.87(b)(3).

²¹ *Id.*

²² Proposed Rule at 32,643-44.

²³ *Id.* at 32,643.

²⁴ *Id.*

²⁵ *Id.* at 32,644.

²⁶ *Id.* at 32,573; 42 C.F.R. § 412.87(b)(2).

²⁷ Proposed Rule at 32,573.

²⁸ *Id.* at 32,573-74.

²⁹ *Id.* at 32,637, 32,644, 32,647, 32,649-50, 32,652.

³⁰ *Id.* at 32,634-52.

³¹ *Id.* at 32,791.

³² *Id.*

³³ *Id.*; 84 Fed. Reg. 65,524 (Nov. 27, 2019). Notably, in December 2019, a group of hospitals and hospital associations filed a lawsuit challenging the new price transparency regulations, arguing that they exceed CMS's statutory authority, violate the First Amendment, and are arbitrary and capricious. The case is pending before the U.S. District Court for the District of Columbia. *American Hospital Association et al. v. Azar*, No. 1:19-cv-3619-CJN (D.D.C. filed Dec. 4, 2019).

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³⁴ Proposed Rule at 32,795-96.

³⁵ *Id.* at 32,791.

³⁶ *Id.* at 32,796-97.

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