ASTCT
American Society for
Transplantation and Cellular Therapy

The following is a DRAFT comment letter still under revision by ASTCT members and will be modified before final submission.

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Executive Summary

ASTCT appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the FY 2026 Inpatient Prospective Payment System (IPPS) Proposed Rule (PR). The following points are a summary of our requests from throughout the letter.

1. MS-DRG 018: Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies

Payment and Rate-setting Proposals

- ASTCT asks that CMS continue use of the modified DRG payment and rate-setting parameters utilized with MS-DRG 018, as the clinical trial pipeline continues to be robust in this area of medicine.
- ASTCT asks CMS to affirm that the agency would expect to see clinical trial billing indicators on expanded access claims, in addition to condition code 90.
- ASTCT asks that CMS modify and clarify the proposed language to be specific to cases where an immunotherapy product "was obtained at no cost," instead of the current language of "not purchased in the usual manner." ASTCT also asks that CMS clarify that this payment adjustment would not be apply to cases where a product was purchased from a manufacturer.
- ASTCT requests that CMS include all drug revenue lines and all types of clinical trial claims, including expanded access cases, for purposes of calculating the median standardized drug charge during an interim period, as this will increase the volume of claims utilized and fully represent the options hospitals have for reporting drug charges. ASTCT also requests that CMS move to identifying these cases through a condition code or other billing indicator going forward, as this will be more reliable than identifying cases through a variable that may change substantially based on what is mapped into MS-DRG 018 at any given time point.

Mapping of Procedure Codes and Products to MS-DRG 018

- ASTCT requests that CMS utilize its established processes to review and reconsider MS-DRG assignment when stakeholders have raised concerns about CMS' assignment, especially in the case of pre-MDC ICD-10-PCS code assignment. ASTCT also continues to request that CMS introduce a process by which stakeholders can see requested MS-DRG mappings as part of or in parallel to the ICD-10-PCS code request process.
- ASTCT asks that CMS further explain recent mappings to MS-DRG 018 so that our members can understand CMS' intent; the implications for hospital payment; and any need for further questions, commentary, and/or guidance on the issue.
- ASTCT requests that CMS not finalize the mapping of valoctogene roxaparvovec to MS-DRG 018 due to differences in clinical complexity and resource use; instead, CMS should use its established mapping process to assign a more clinically homogenous DRG.
- ASTCT asks that CMS clarify why the discussion of a new neurosurgical gene therapy MS-DRG was included in the MS-DRG 018 discussion and what information the agency seeks from stakeholders in advance of the FY 2027 IPPS cycle.

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Future Rate-Setting Comments

- ASTCT requests that CMS considers way to mitigate ongoing charge compression as part of its analysis of stakeholder feedback related to future payment for cell and gene therapies.
- ASTCT asks that CMS conduct or commission a pilot study that examines the effect of including Medicare Advantage (MA) shadow claims with FFS claims on IPPS rate-setting for the Pre-MDC MS-DRGs. We additionally request that CMS release all claims data used in the study, including data for both MA and fee-for-service (FFS) encounters, to aid in independent stakeholder analysis.

2. MS-DRG 014: Allogeneic Bone Marrow (Stem Cell) Transplantation

- ASTCT asks that CMS clarify why certain stem cell transplant procedures have been mapped to MS-DRG 018 instead of MS-DRG 014.

3. MS-DRG 016 & 017: Autologous Bone Marrow (Stem Cell) Transplant with/without CC/MCC

- Given the advancement and implementation of the Center for Medicare and Medicaid Innovation's (CMMI) Cell and Gene Therapy (CGT) Model, ASTCT asks that CMS reassess whether a mechanism can be established by which Medicare beneficiaries with Sickle Cell Disease, particularly dual-eligible beneficiaries, can participate in order to ensure coverage for beneficiaries and adequate reimbursement for hospitals.
- ASTCT assumes the DRGs 016 and 017 were mistakenly listed in the discussion of non-monotonicity for FY 2026, but asks CMS to confirm that this is the case in the final rule.

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MS-DRG 018: Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies

ASTCT continues to invest significant time and resources in educating its members on CMS' coverage, coding, billing, and reimbursement provisions. We do this by conducting webinars and through the release of a *CAR-T Coding & Billing Guide* to highlight and consolidate CMS' instructions for hospitals.[1] ASTCT appreciates the on-going attention CMS places on MS-DRG 018 as the use of cell and gene therapies continues to expand through approvals by the Food and Drug Administration (FDA).

Payment and Rate-Setting Proposals

Proposal to Continue Payment Adjustment for Expanded Access and Clinical Trial Cases

In the Proposed Rule (PR), CMS states:

> *For FY 2026, we are proposing to continue to apply an adjustment to the payment amount for expanded access use of immunotherapy and applicable clinical trial cases that group to MS– DRG 018, calculated using the same methodology, as modified in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59062), that we are proposing to use to adjust the case count for purposes of the relative weight calculations, including our proposed modifications to that methodology for FY 2026, as described in section II.D. of the preamble of this proposed rule.*[2]

ASTCT continues to appreciate the unique rate-setting methodological changes CMS has implemented for MS-DRG 018, and its recognition that a significant number of the cases assigned to MS-DRG 018 are clinical trial cases.

ASTCT asks that CMS continue use of the modified DRG payment and rate-setting parameters utilized with MS-DRG 018, as the clinical trial pipeline continues to be robust in this area of medicine.

Throughout this and prior rules, CMS seems to differentiate between clinical trial and expanded access cases by using 'or' and 'and' in a manner that indicates expanded access cases are uniquely different from clinical trial cases. ASTCT's understanding, however, is that expanded access use of CAR-T or other therapies that are mapped to MS-DRG 018 has to occur as part of

[1] American Society for Transplantation and Cellular Therapy (ASTCT), *ASTCT CAR-T Coding & Billing Guide,* Chicago (IL): ASTCT, no date. *Online*: https://www.astct.org/advocate/car-t-coding-and-billing-guide.

[2] Centers for Medicare & Medicaid Services (CMS), "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 2026 Rates; Quality Programs Requirements; and Other Policy Changes: Proposed Rule," *Federal Register*, 2025; 90 (82): 18282. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page. (Hereafter: CMS, *CMS FY 2026 IPPS Proposed Rule*.)

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an expanded access Investigational New Drug (IND) study.[3] This type of clinical trial qualifies for coverage under NCD 310.1 – *Routine Costs in Clinical Trials*.[4] As such, ASTCT believes that both condition code 90 and all appropriate clinical trial indicators (e.g., Z00.6, value code D4, condition code 30) should be added to expanded access claims in order to indicate that they are also qualifying clinical trial claims per NCD 310.1.

ASTCT asks CMS to affirm that the agaency would expect to see clinical trial billing indicators on expanded access claims, in addition to condition code 90.

Proposal to Modify Payment for Certain Immunotherapy Cases

In the FY 2026 PR, CMS proposes to modify payment for certain immunotherapy cases, in response to a request associated with the 2025 rule-making cycle.

> *In the FY 2025 IPPS/LTCH PPS final rule, we summarized a comment requesting that CMS establish a mechanism for hospitals to report when a product is not purchased in the usual manner, such as obtained at no cost, for reasons other than participation in a clinical trial or expanded access use (89 FR 69112). We indicated we may consider this request in future rulemaking. We agree that the same adjustment that applies to expanded access use of immunotherapy and applicable clinical trial cases should apply to other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, and therefore are proposing that, beginning in FY 2026, the payment adjustment would also be applied in calculating the payment for such cases.*
>
> *We intend to issue billing instructions in separate guidance that would allow a provider to indicate, for that case, that the immunotherapy product was not purchased in the usual manner so that MACs would apply the same adjustment to the payment amount that is applied for expanded access use of immunotherapy and applicable clinical trial cases that group to MS– DRG 018.* [5]

ASTCT reviewed the public comment indicated by CMS and notes that the stakeholder letter utilized different terminology than is contained in CMS' current proposal. The comment letter used the suggested language of "CAR-T and other immunotherapies obtained at no cost" to identify cases that do not fit with the current clinical trial and expanded access definitions—such as a product being provided through a manufacturer's patient assistance program (PAP).

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[3] U.S. Food & Drug Administration (FDA), *IND Applications for Clinical Treatment (Expanded Access),* Rockville (MD): FDA, Online: https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-applications-clinical-treatment-expanded-access-overview.
[4] CMS Medicare Coverage Database, National Coverage Determination: Routine Costs in Clinical Trials, 310.1, Baltimore (MD), CMS, 2024. Online: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1.
[5] CMS, *CMS FY 2026 IPPS Proposed Rule*, pages 18282-18283. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page.

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ASTCT understands and supports the identification of PAP cases for purposes of the adjusted payment as well as other limited scenarios where no product cost was incurred. ASTCT does not support the current description of such cases by CMS as "not purchased in the usual manner," however. A primary issue with this description is that a product obtained at no cost is inherently not "purchased" in any manner; these cases do not involve payent and, therefore, are not *purchases*. Instead, the immunotherapy product is obtained through a no cost mechanism available through the manufacturer.

Additionally, the term "not in the usual manner" is problematic; it is vague and subjective, and leaves centers open to a variety of interpretations from Medicare Administrative Contractor (MAC). ASTCT asks CMS to modify the language in keeping with the original request for the agency to more accurately and clearly specify the types of cases that should have this payment adjustment applied (e.g., "cases where the immunotherapy is obtained at no cost"). ASTCT also asks CMS to clarify that this adjustment does not apply to any situation when an immunotherapy product is purchased by a hospital, irrespective of when it is administered, in recognition that a product purchased at one point in time may be given across multiple encounters.

ASTCT also notes that CMS intends to release billing guidance to indicate when cases have obtained an immunotherapy product at no cost. ASTCT supports CMS releasing a new condition code to improve clarity in the claims data. This would be similar to the release of condition code 90, and would help isolate expanded access cases as a specific subtype of clinical trial. A new condition code would flag that the "product was obtained at 'no cost'," such as instances where a hospital receives a product for a specific patient without an associated cost. We agree with CMS that such use claims should not be used for rate-setting since they would distort rate-setting , similar to clinical trial and expanded access cases, given the difference in resource use compared to cases in which the immunotherapy was purchased.

ASTCT asks that CMS modify and clarify the proposed language to be specific to cases where an immunotherapy product "was obtained at no cost" instead of the current language of "not purchased in the usual manner." ASTCT also asks that CMS clarify that this payment adjustment would not be apply to cases where a product was purchased from a manufacturer.

Proposal to Modify Rate-setting for Certain Immunotherapy Cases

CMS made a second proposal in the rule related to a subset of immunotherapy cases:

> *To mirror this proposed change within our relative weight methodology, we are proposing to also exclude claims with standardized drug charges below the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 (that is, claims that contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code*

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> *''ZC'') when we calculate the average cost for MS–DRG 018. For this proposed rule, based on the December 2024 update of the FY 2024 MedPAR file, we estimate that the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 (that is, claims that contain ICD–10– CM diagnosis code Z00.6 and do not include payer-only code ''ZC'') is $29,819. We are proposing to apply this policy for 2 years (that is, in our relative weight methodology for MS–DRG 018 for FYs 2026 and 2027), until the claims data reflects the addition of the condition code indicating that the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, which then would be able to be used to identify these cases such that they can be identified for exclusion from the calculation of the average cost of MS–DRG 018. We are also proposing, for the purpose of performing this trim, to update the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 based on more recent data for the final rule. Accordingly, we are proposing that in calculating the relative weight for MS– DRG 018 for FY 2026, in identifying clinical trial claims and expanded access use claims and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, only those claims that group to MS–DRG 018 that (1) contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'', (2) contain condition code ''90'', or (3) contain standardized drug charges below the median standardized drug charge of clinical trial cases in MS–DRG 018 would be excluded from the calculation of the average cost for MS-DRG 018.*[6]

ASTCT is generally supportive of CMS' proposed interim rate-setting proposal until cases can be identified through a future condition code. Yet, ASTCT has the following questions for CMS:

- Does the median standardized drug charge represent all drug revenue lines, including 25x, 63x and 0891?
- When CMS states that the median standardized drug charge is from "claims identified as clinical trials," does this also include expanded access cases?

ASTCT requests that CMS include all drug revenue lines and all types of clinical trial claims, including expanded access cases, for purposes of calculating the median standardized drug charge during an interim period. Doing so will increase the volume of claims utilized and fully represent the options hospitals have for reporting drug charges.

ASTCT also requests that CMS move to identify these cases through a condition code or other billing indicator going forward. Doing so will be more reliable than identifying cases through a variable that may change substantially based on what is mapped into MS-DRG 018 at any given time point.

[6] CMS, *CMS FY 2026 IPPS Proposed Rule*, page 18079. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page.

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CMS Request for Input on Clinical Trial Cases with Drug Charges Similar to Non-Trial Cases

In its discussion of proposed modification to rate-setting for certain immunotherapy cases, CMS notes:

> *With respect to claims that group to MS–DRG 018 and are identified as clinical trials or involve expanded access use of the CAR T-cell therapy or other immunotherapy, we note that there are some cases that appear to include drug charges similar to cases not identified as clinical trials or involving expanded access use. These charges are generally in revenue center 0891, Cell Therapy Drug Charges. We are seeking comments on potential reasons for why claims identified as clinical trials or involving expanded access use, in which the provider would typically receive the product at no cost, would have charges in revenue center 0891, Cell Therapy Drug Charges.*[7]

ASTCT is glad CMS is looking closely at the data and has identified this issue. Without information on volume or the procedure codes involved, however, it is difficult to assist CMS with further investigating the specific cases of interest. It is possible that the cases may have been miscoded in some manner, particularly if when they involve a purchased immunotherapy product and a clinical trial of a different drug that is being used as part of the patient care regimen. CMS does not currently require a condition code or specific billing indicator for the claims; instead, the agency instructs hospitals to utilize the remarks field to identify these clinical cases, which may increase the likelihood of incomplete coding.

Mapping of Procedure Codes and Products to MS-DRG 018

Clarification on Submitting Comments for Potential Mappings

ASTCT appreciates the the clarification CMS provided regarding the submission of comments related to coding requests presented during the Spring ICD-10 Coordination and Maintenance Committee Meeting. We also appreciate the clarification that comments submitted after that meeting will be shared with the groups responsible for considering MS-DRG mappings.

ASTCT notes that it may be reasonable to expect stakeholders to review meeting materials and submit comments accordingly, when needed. It should not, however, be stakeholders' responsibility to present an alternative mapping for a code. Commenters may have the expertise to identify when a new procedure code does not match the clinical homogeneity of a specific DRG, but lack the broader clinical expertise required to propose an alternative detailed mapping. CMS has noted multiple times that it relies upon medical advisors that utilize standard processes to identify potential mappings, which ASTCT supports.

[7] CMS, *CMS FY 2026 IPPS Proposed Rule*, page 18079. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page.

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ASTCT requests that CMS utilize its established processes to review and reconsider MS-DRG assignment when stakeholders have raised concerns about CMS' assignment, especially in the case of pre-MDC ICD-10-PCS code assignment. ASTCT also continues to request that CMS introduce a process by which stakeholders can see requested MS-DRG mappings as part of, or in parallel to, the ICD-10-PCS code request process.

Request for Rationale for Mapping Certain Therapies to MS-DRG 018

ASTCT appreciates that CMS shared the types of concerns and questions raised by stakeholders about the agency's rationale for mapping new ICD-10-PCS codes for novel therapies into MS-DRG 018. We empathize with CMS' workload on evaluating each new procedure code request for all new cell and gene therapy approvals, but remain frustrated that the agency still has not engaged in a detailed discussion about the methodology or rationale its medical advisors use to assign these codes into MS-DRG 018.

Despite the extended discussion of stakeholder concerns about increased transparency and opportunity for comment on potential mappings, CMS neither mentions nor discusses its proposed mapping of valoctocogene roxaparvovec into MS-DRG 018, other than by listing it in Table 6B, despite the fact that this therapy is neither a CAR-T product nor an immunotherapy. Additionally, while CMS addressed some questions raised by stakeholders about recent mapping decisions, the agency did not respond to others. ASTCT members continue to be interested in CMS' rationale for mapping certain therapies provided as part of a stem cell transplant in alignment with the procedure being performed to deliver the therapy (i.e. HSC gene therapies mapped to MS-DRGs 016 and 017, or omidubicel mapped to MS-DRG 014), but mapping other therapies (such as Orca-T) based on a different (and unexplained) rationale.

ASTCT asks CMS to further explain these recent mappings to MS-DRG 018 so that our members can understand CMS' intent; the implications for hospital payment; and the need for further questions, commentary, and/or guidance on the issue.

Proposed Mapping of Valoctocogene Roxaparvovec to MS-DRG 018

As noted earlier in these comments, CMS proposes to map valoctocogene roxaparvovec to MS-DRG 018 via Table 6B. The agency does not, however, provide any rationale in the text of the PR for this proposal. Valoctocogene roxaparvovec is an off-the-shelf *in vivo* gene therapy that is neither a CAR-T nor an immunotherapy, and does not require the same types of complex and specialized clinical resources to administer as the other therapies assigned to MS-DRG 018. For this reason, ASTCT disagrees with CMS' proposed mapping and request that the agency provide its rationale in the final rule. In the absence of other supporting rationale, ASTCT assumes that the manufacturer requested the mapping to MS-DRG 018 as part of its ICD-10-PCS code request application and is basing that request solely on the $2.9M price of the therapy and the MS-DRG relative weight.

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ASTCT requests that CMS not finalize the mapping of valoctogene roxaparvovec to MS-DRG 018 due to differences in clinical complexity and resource use; instead, CMS should use its established mapping process to assign valoctogene roxaparvovec to a more clinically homogenous DRG.

Discussion of New Neurosurgical Gene Therapy MS-DRG

In the discussion of MS-DRG 018, CMS describes a stakeholder request to create a new MS-DRG for neurosurgical gene therapies. CMS does not discuss a secondary request for the main therapy of discussion, eladocagene exuparvovec, to be mapped to MS-DRG 018. Therefore, it is unclear why this therapy was discussed within the context of MS-DRG 018 and not in the context of MDC 10 and the associated MS-DRGs to which it is mapped, as it has been in prior rulemaking cycles.[8]

It is also unclear if CMS placed this discussion within MS-DRG 018 in an effort to seek comments about whether MS-DRG 018 should be broadenend to included this and other gene therapies. If CMS is seeking comment on an expansion of this manner by raising this issue and mapping eladocagene exuparvovec (an *in vivo* gene thearpy) to MS-DRG 018, ASTCT asks CMS to make this explicit and seek feedback in advance of the FY 2027 IPPS rulemaking cycle. If CMS intends for MS-DRG 018 to be the primary MS-DRG for all cell and gene therapies until further subdivisions can be made based on case volume, the agency should propose to rename the DRG and be consistent with mapping practices and rationale.

Finally, ASTCT notes that, while CMS notes that it did not find any cases with eladocagene exuparvovec in the FY 2024 MedPAR file, the product was not approved until November 2024 and, thus, would not be expected to appear in the data. Rare disease therapies that seek re-mapping after initial placement are caught in a difficult cycle of being very low-volume and potentially more likely to be utilized by MA patients, where hospitals are able to seek and receive prior authorization before treatment, compared to traditional Medicare. In a subsequent section of this comment letter, ASTCT provides suggestions on the use of MA data to increase the volume of cell and gene therapy cases available for CMS' review.

ASTCT asks that CMS clarify why the discussion of a new neurosurgical gene therapy MS-DRG was included in the MS-DRG 018 discussion and what information the agency seeks from stakeholders in advance of the FY 2027 IPPS cycle.

[8] CMS, "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 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access: Final Rule," *Federal Register*, 2022; 87(153), pages 48853-48854. Online: Final Rule. (Hereafter: CMS, "Medicare Program Hospital IPPS Final Rule," *Federal Register*, 2022; 87:153.)

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Future Rate-Setting Comments

Charge Compression Continues to Suppress the MS-DRG 018 Relative Weight

In the FY 2025 IPPS Final Rule, CMS responded to concerns from ASTCT and other stakeholders that cases using high-cost products are being routinely unpaid—and to an exceptional amount compared to other services and MS-DRGs. CMS states:

> *As described in the FY 2005 IPPS final rule (69 FR 49003), even if a technology does not receive new technology add-on payments, CMS continues to pay for new technologies through the regular payment mechanism established by the DRG payment methodology. In addition, the costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to* ***unusually expensive cases*** *[emphasis added]. Any eligible outlier payment is added to the DRG-adjusted base payment rate (88 FR 58648).*[9]

ASTCT reiterates our concerns about charge compression for MS-DRG 018 cases for exactly the reason CMS identifies above—the majority of cases in MS-DRG 018 receive substantial outlier dollars; thus, they are *not* unusually expensive within their own cohort. We have also further described our position and concerns about an insufficient base payment for MS-DRG 018 in our comment letters on the FY 2024 and FY 2025 IPPS PRs.[10]

Because hospitals are required to follow uniform charging practices, their chargemasters must reflect the highest charge necessary to be aligned with CMS' guidance on charging and processing these charges as part of the IPPS. The concerns related to charge compression and the resulting need for hospitals to utilize very high charges for already high-cost drugs are of increasing concern given the focus on price transparency, including financial penalties for high-dollar charges.[11] Below, we reitered our prior recommendations and provide updated numbers for this rule-making cycle. We urge CMS to implement changes in order to not only pay hospitals adequately for the care they provide but also decrease outlier spending.

ASTCT notes that the primary driver of the high costs associated with MS-DRG 018 is not clinical care costs; rather, it is the product acquisition cost, which is beyond providers' control. CMS' rate-setting methodology cannot adequately account for this cost despite the unique rate-setting methodology being used (i.e., setting aside clinical trial and expanded access cases). This underpayment trend continues year-over-year, despite providers heeding CMS' guidance that

[9] CMS, *Acute Inpatient PPS*, Baltimore (MD), CMS, April 14, 2025, pages 631-632. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.
[10] ASTCT, *ASTCT Policy Letters and Statements*, Chicago (IL): ASTCT, no date. Online: https://www.astct.org/Advocacy/Policy-Letters-and-Statements.
[11] Cass A, "Indiana governor signs law penalizing high hospital prices," *Becker's Hospital Review,* May 8, 2025. Online: https://www.beckershospitalreview.com/finance/indiana-governor-signs-law-penalizing-high-hospital-prices/.

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they can set charges in accordance with their cost-to-charge ratios (CCRs)[12] given the significant charge compression that occurs.

Within the agency's discussion of a potential modification to payment for certain immunotherapy cases, CMS shares the average costs of cases assigned to MS-DRG 018 after clinical trial cases have been removed.

> *Under our proposal to continue to apply this methodology, with the proposed modification as described, based on the December 2024 update of the FY 2024 MedPAR file used for this proposed rule, we estimated that the average costs of cases assigned to MS– DRG 018 that are identified as clinical trial cases ($88,484) were 23 percent of the* ***average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($385,147).***[13]

CMS' calculation of an average case cost of $385,147 exemplifies the on-going issues associated with charge compression and the high-cost immunotherapy products provided: the average cost for hospitals to acquire the products assigned to MS-DRG 018 exceeds $500,000 before any clinical care is provided. If the total true case costs for a hospital are reduced to a calculated cost of less than the product purchase price, there must be significant methodological issues with IPPS payment calculations.

Despite the unique payment and rate-setting practices CMS has implemented for MS-DRG 018, our analysis of the FY 2026 PR data files includes the following indications that the base payment rate remains significantly out of alignment with true case costs, even with the proposed increase for FY 2026:

- 952 of 1,447 cases (65%) received outlier dollars.
- $200,287,834 total outlier dollars were spent on these 952 outlier cases, representing 27% of the total payments made for MS-DRG 018 cases.

For context, the MS-DRG with the next-highest outlier proportion is MS-DRG 001, *Heart Transplant or Implant of Heart Assist System with MCC*, with an outlier case percentage of 41.3%. The range of percentage of outlier cases in all remaining Pre-MDC MS-DRGs is between 6.6-38.8%, indicating that MS-DRG 018 is an outlier amoung outliers, even within the Pre-MDCs.

ASTCT requests that CMS considers way to mitigate ongoing charge compression as part of its analysis of stakeholder feedback related to future payment for cell and gene therapies.

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[12] CMS, "Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program: Final Rule," *Federal Register*, 2021; 86 (154), page 192. Online: https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf.

[13] CMS, *CMS FY 2026 IPPS Proposed Rule*, page 18080. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page.

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Study Medicare Advantage Shadow Claims Use to Increase Cell and Gene Therapy Case Data

ASTCT appreciates that CMS states it is *"in the process of carefully considering the feedback we have previously received about ways in which we can continue to appropriately reflect resource utilization while maintaining clinical coherence and stability in the relative weights under the IPPS MS–DRGs."*[14]

In several of ASTCT's prior comment letters, we have requested that CMS study the potential impact of MA shadow claims on rate-setting for cell and gene therapies.[15] CMS responded with the following statement in the FY 2024 Final Rule:

> *Response: We appreciate the commenters' feedback. We acknowledge the growth in Medicare Advantage claims and will continue to review and consider the feedback we have received for our development of the FY 2025 proposed rule.*[16]

Although further action was not taken in the FY 2025 PR, ASTCT was heartened that CMS is proposing to utilize MA data in its evaluation of the Hospital Readmissions Reduction Program beginning in FY 2027. CMS states:

> *Including MA beneficiaries in hospital outcome measures would help ensure that hospital quality would be measured across all Medicare beneficiaries and not just the Fee-ForService (FFS) population. In 2024, 50 percent of eligible Medicare beneficiaries—or 34.3 million people— were covered by MA plans. It is projected that nearly two-thirds of Medicare enrollees will be enrolled in MA plans by 2030. Consequently, using FFS-only beneficiaries may exclude a large segment of the focus population for quality measurement.*[17]

The ASTCT strongly supports CMS' intent to include MA beneficiaries for the purpose of creating more comprehensive and representative data. We ask CMS to revisit the potential for study and potential inclusion of these claims for rate-setting, particularly for cell and gene therapies and other rare disease treatments. As the percent of beneficiaries enrolled in FFS

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[14] CMS, *CMS FY 2026 IPPS Proposed Rule*, page 18017. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page.

[15] ASTCT, *ASTCT Policy Letters and Statements: FY 2024 IPPS Proposed Rule Comment Letter*, Chicago (IL): ASTCT, June 9, 2023. Online: https://www.astct.org/Advocacy/Policy-Letters-and-Statements.

[16] CMS, "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 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership; and Medicare Disproportionate Share Hospital (DSH) Payments: Counting Certain Days Associated With Section 1115 Demonstrations in the Medicaid Fraction: Final Rule," *Federal Register*, 2023; 88(165), page 20. Online: https://www.govinfo.gov/content/pkg/FR-2023-08-28/pdf/2023-16252.pdf,.

[17] CMS, *CMS FY 2026 IPPS Proposed Rule*, page 18284. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page.

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decreases, the number of FFS claims used for the rate-setting process will also decrease and become less representative for predicting resource utilization; this will worsen the problem of limited claims for cell and gene therapies and/or rare disease treatments.

In the FY 2024 MedPAR data utilized for FY 2026 IPPS rate-setting, there were at least 810 MA claims for MS-DRG 018 (an increase from 390 in the FY 2023 data), an amount that is almost equal to that used in rate-setting. Similarly, there were more than 2,000 MA SCT claims (an increase from 1,600 in the FY 2023 data), which accounts for more than 43% of the total volume of transplants provided to Medicare beneficiaries during that time period.[18] Setting aside a very significant—and growing—percentage of cases each year is extremely problematic for low-volume, rare-disease therapies.

A higher volume of claims should make CMS' analyses of claims more statistically robust. It should also ensure that both FFS payments and IPPS benchmarks used by MA plans are more representative of the full range of patients treated and the care they receive from IPPS hospitals. Additionally, a higher volume of claims could help the agency further explore appropriate mechanisms to address therapies that represent low volumes of claims data, as previously discussed in Rare Disease RFI summary within the FY 2023 Final Rule.[19] CMS already has access to the data needed to examine the effect of MA inclusion on these issues, given that hospitals that bill an MA plan for an inpatient stay must also submit a copy of that claim to their local MAC for informational purposes, known as a "shadow claim."

ASTCT asks CMS to conduct or commission a pilot study that examines the effect of including MA shadow claims with FFS claims on IPPS rate-setting for the Pre-MDC MS-DRGs. We additionally request that CMS release all claims data used in the study, including data for both MA and FFS encounters, to aid in independent stakeholder analysis.

MS-DRG 014: Allogeneic Bone Marrow (Stem Cell) Transplantation

As raised in our earlier discussion of rationale behind mapping products to MS-DRG 018, **ASTCT asks that CMS clarify why certain stem cell transplant procedures have been mapped to MS-DRG 018 instead of MS-DRG 014.** ASTCT would be eager and willing to meet with CMS to discuss the innovation in stem cell transplant, including modified and/or engineered graft sources.

MS-DRG 016 & 017: Autologous Bone Marrow Transplant w/ and w/o CC/MCC

[18] CMS, *MedPAR Hospital National Limited Data Set*, FY 2023 and FY 2024, Baltimore (MD): CMS, April 14, 2025. Online: https://www.cms.gov/data-research/files-for-order/limited-data-set-lds-files/medpar-limited-data-set-lds-hospital-national.
[19] CMS, "Medicare Program Hospital IPPS Final Rule," *Federal Register*, 2022; 87(153), page 75. Online: https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-16472.pdf,.

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Future State for HSC Gene Therapies Mapped to MS-DRGs 016 and 017

As of FY 2025, there are multiple hematopoietic stem cell (HSC) gene therapies mapped to MS-DRGs 016 and 017, the DRGs that best describe the clinical services being performed when administering these innovative products as part of a stem cell transplant. Both ASTCT and other stakeholders have commented in prior rule cycles, however, that these MS-DRGs cannot be a long-term solution for the resource utilization associated with multi-million dollar therapies. This is particularly true when the New Technology Add-on Payment (NTAP) expires for the products indicated for sickle cell disease, as is expected to happen after the FY 2027 cycle. Without NTAP, hospitals will experience staggering losses when providing these therapies under IPPS, given the tremendous portion of the case cost that will be paid through the outlier formula. No current MS-DRG in the system will be suffificent to support sustained and geographically dispersed access for these critical and potentially life-saving therapies needed by beneficiaries.

In the FY 2025 IPPS Final Rule, CMS included the following statement in its discussion of a request associated with a gene therapy:

> *We further note that, in response to the President's Executive Order 14087, "Lowering Prescription Drug Costs for Americans", a Cell and Gene Therapy (CGT) Access Model was developed, which could help inform future inpatient payment policy for cell and gene therapies more generally.*[20]

CMMI has made significant advancements with the CGT Access Model, recently indicating that 84% of Medicaid beneficiaries with Sickle Cell Disease will be represented by the 35 states electing to participate.[21] CMS has not yet, however, indicated how Medicare beneficiaries could participate in the Model or describe an equivalent model to be implemented in the Medicare population. In the Question & Answer portion of CMMI's February 6, 2024 webinar, CMMI staff stated:

> *We are working closely with our colleagues in the Center for Medicare to ensure alignment between what we're doing here in the model as far as coverage and reimbursement policies and what the Center for Medicare is doing as far as coverage. And reimbursement, but they have their own process and timeline and we are working in parallel and trying to ensure harmony.*[22]

[20] CMS, *Acute Inpateint PPS*, Baltimore (MD), CMS, pages 75-77. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.
[21] CMS, *Cell and Gene Therapy (CGT) Access Model*, Baltimore (MD), CMS, no date. Online: https://www.cms.gov/priorities/innovation/innovation-models/cgt.
[22] CMS, *Transcript from Webinar: CGT Access Model Overview*, Baltimore (MD): CMS, February 6, 2024. Online: https://www.cms.gov/files/document/cgt-modelovw-webinar-2-6-24-transcript.pdf

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Given the advancement and implementation of the CMMI CGT Model, ASTCT asks CMS to reassess whether a mechanism can be established by which Medicare beneficiaries with Sickle Cell Disease, particularly dual-eligible beneficiaries, can participate in order to ensure coverage for beneficiaries and adequate reimbursement for hospitals.

Non-Monotonicity of MS-DRGs 016 and 017

ASTCT notes that CMS mentions MS-DRGs 016 and 017 in its discussion of non-monotonicity in a base MS-DRG, and acknowledges that these MS-DRGs were non-monotonic for the past two Fiscal Years. CMS' Tables/relative weight files propose two different payment rates for these DRGs, however, indicating that non-monotonicity would not apply.[23]

ASTCT assumes DRGs 016 and 017 were mistakenly listed in the discussion of non-monotonicity for FY 2026 and asks that CMS confirm that this is the case in the final rule.

ASTCT appreciates CMS' review of our comments and would be pleased to engage on any technical questions the agency may have.

[23] CMS, *CMS FY 2026 IPPS Proposed Rule*, page 18078. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page.

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