ASTCT
American Society for
Transplantation and Cellular Therapy

This document contains submitted ASTCT comments and selections from CMS' responses in the FY 2026 IPPS Final Rule, dated July 31, 2025. As such, the Executive Summary has been removed from this version.

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

June 10, 2025

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the LongTerm Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes [CMS-1833-P]

Dear Administrator Oz:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit the following comment letter regarding the FY 2026 IPPS Proposed Rule.

ASTCT is a professional membership association of more than 3,900 physicians, scientists, and other health care professionals promoting hematopoietic stem cell transplantation (SCT) and cellular therapy through research, education, scholarly publication, and clinical standards. Our Society's clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current Food and Drug Administration (FDA) approvals for chimeric antigen receptor T-cell (CAR-T) therapy and hematopoietic stem cell (HSC) gene therapies for genetic immune system and blood disorders. For more than 25 years, ASTCT members have focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases.

ASTCT would welcome the opportunity to meet with CMS and discuss ways to improve payment for CAR-T, SCT, and gene therapies.

If CMS has any questions regarding these comments, please contact Alycia Maloney, ASTCT's Director of Government Relations, at amaloney@astct.org.

David Porter, MD
President, ASTCT
2025-2026

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This document contains submitted ASTCT comments and selections from CMS' responses in the FY 2026 IPPS Final Rule, dated July 31, 2025.

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 by publishing 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 PR and prior rules, CMS seems to differentiate between clinical trial and expanded access cases by using "or" and "and" in a manner that could suggest that the agency sees expanded access cases as uniquely different from clinical trial cases. We do not believe that is the case or CMS' intent since expanded access use of CAR-T or other therapies that are mapped to MS-DRG 018 must occur as part of an Investigational New Drug (IND) study[3], which would have a National Clinical Trial number and would meet criteria for routine costs of the clinical trial NCD 310.1.

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[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*.)

[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.

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However, given that CMS seems to differentiate between expanded access and clinical trials, ASTCT continues to receive questions from providers about which billing indicators are applicable. In order to eliminate provider confusion, **ASTCT requests that CMS confirm that expanded access claims should be reported with the clinical trial diagnosis code Z00.6, condition code 30, value code D4 and the NCT number, in addition to condition code 90 which specifically helps identify which clinical trial claims are expanded access claims.** This clarification from CMS will help eliminate any provider question or confusion around CMS' coverage intent for expanded access cases, similar to other clinical trial cases, under NCD 310.1 – *Routine Costs in Clinical Trials*.[4]

CMS Response: ***Comment:*** *A few commenters expressed confusion about CMS' differentiation between clinical trial and expanded access use cases. A commenter stated that it does not believe this differentiation is CMS' intent because expanded access use of CAR T-cell or other therapies that are grouped to MS-DRG 018 must occur as part of an Investigational New Device (IND) study, which would have a National Clinical Trial number and would meet criteria for routine costs of the clinical trial NCD 310.1. This commenter cited the FDA website in support of these statements. Another commenter requested that CMS clarify that expanded access cases are a type of clinical trial.*

A commenter requested that CMS clarify that expanded access use would also be excluded from ratesetting because facilities do not incur the cost of these products. A few commenters requested that CMS clarify that the agency would expect to see clinical trial billing indicators on expanded access claims (that is, diagnosis code Z00.6, condition code 30, value code D4, and the NCT number), in addition to condition code 90, which would help identify which clinical trial claims are expanded access claims.

Response: *The FDA states, at the link provided by the commenter, "Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options". While we utilize separate condition codes to identify clinical trial claims and expanded access use cases, we note that they are treated the same for payment purposes and in the calculation of the relative weights for MS-DRG 018.* [FR 36655]

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 prior 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*

[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.

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> *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 "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).

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, however, understand what CMS means by, "*product is not purchased in the usual manner, such as obtained at no cost."* While "obtained at no cost" is clear and an appropriate description (e.g., no money changed hands), *"product not purchased in the usual manner"* is inaccurate. A product is either purchased or obtained at no cost; if there is no cost, then there is no purchase. If products were obtained at no cost, the ASTCT agrees that these cases would not involve product payment from CMS; instead, they would generate the reduced MS-DRG 018 rate for patient care costs only. The term "*not in the usual manner*" is additionally problematic because "usual manner" is highly subjective. When CMS statements are vague or unclear it can cause confusion and undue administrative burden for providers, while creating varying (and possibly conflicting) interpretations by Medicare Administrative Contractors (MACs), all of which could have inadvertent coding, billing, and payment impact.

ASTCT requests that CMS modify its language to match the intent of the original commenter's request - cases where the immunotherapy "is obtained at no cost".

Certain immunotherapy products may be administered across multiple encounters. In situations where multiple administrations of the single product must be given, CMS cannot assume that the full cost would always be attributed to the primary administration and that there would be no product cost for the subsequent administrations. **As such, ASTCT also asks CMS to confirm that a reduced payment of MS-DRG 018 does not apply when a hospital purchases an immunotherapy product (i.e., incurs a cost), irrespective of whether it is administered in multiple encounters.** This clarification would recognize that product costs were incurred, given that the provider purchased the product from the manufacturer. *If CMS has specific requirements or expectations for how providers should submit charges for these situations, then the agency should either clarify them or state that it is up to each provider to determine how best to develop charges for multiple administrations of a single product that is purchased from the manufacturer (per the Provider Reimbursement Manual).*

[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 assumes that CMS' forthcoming billing guidance will contain the new condition code CMS mentions in its discussion. **ASTCT supports the use of a condition code to improve clarity in the claims data in order to capture instances where a hospital receives a product for a specific patient without an associated cost.**

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

- 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, to calculate 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.

[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 Response: ***Comment*** *(pg. 36654): Commenters supported our proposal to exclude claims in MS-DRG 018 with standardized drug charges below the median standardized drug charges of cases identified as clinical trials in MS-DRG 018. Commenters stated that this proposal ensures that clinical trial and no-cost cases do not distort payment rates across the IPPS. We note a commenter mistakenly referred to our existing policy as still excluding cases that have a standardized drug charge of less than $373,000.*

Commenters requested clarification about whether the median standardized drug charges includes all drug revenue lines and all clinical trial claims, including expanded access claims. Some commenters expressed support for the identification of cases involving patient assistance programs, where no cost is incurred, but expressed confusion regarding the language "product not purchased in the usual manner", stating that is subjective, which can lead to confusion and undue administrative burden for providers and varying interpretations by the MACs. A commenter requested that CMS modify the language to reflect the request in the comment summarized in the FY 2025 IPPS/LTCH PPS final rule, which referred to cases where the immunotherapy is "obtained at no cost".

Response: *We appreciate commenters support for our proposal. While we indicated in the proposed rule that we calculate the median standardized drug charges for cases identified as clinical trial claims including cases that contain ICD-10-CM diagnosis code Z00.6 and do not include payer only code ZC, we note that in calculating the median standardized drug charges for cases identified as clinical trial claims, we included claims that (a) contain ICD–10–CM diagnosis code Z00.6 and do not contain condition code "ZC" or (b) contain condition code "90". Just as we treat cases identified as clinical trial cases and expanded access use cases in the same manner for payment purposes and in the calculation of the relative weights, we are also including both claims identified as clinical trial cases and claims identified as expanded access use cases in calculating the median drug charges. Since the provider does not incur the cost of the drug in cases identified as clinical trial cases or expanded access use cases, but still incurs costs for other drugs during the inpatient stay, we believe that using the median standardized drug charge for clinical trial and expanded access use cases would appropriately identify other cases involving products not purchased in the usual manner. The drug revenue lines are the same as those used in the relative weight calculations, which are shown in the Cost Center HCRIS Lines Supplemental Data File referenced earlier in this section.*

With respect to the commenters who expressed concerns about the language "product not purchased in the usual manner", we note that this phrasing is not new; we have used the language "product is purchased in the usual manner" in prior rules with respect to MS-DRG 018. Furthermore, we believe that this language is appropriately phrased to include the broad range of scenarios that may fall under it. For example, as described later in this section, commenters raised the possibility of immunotherapy products administered over multiple encounters. Given that we cannot predict all possible scenarios where the product is not purchased in the usual manner, use of a condition code that reflects a broad array of circumstances will facilitate more accurate payment and ratesetting. We further note that the "usual manner" in which a product is purchased may differ for products administered in one dose versus split doses. [FR 36654]

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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. However, the description of these cases fits the profile of cases that involve a clinical trial of a product *other than the immunotherapy being utilized* – i.e. something that may be used to treat or prevent complications associated with the immunotherapy itself. For these types of cases, providers enter "Diff Prod Clin Trial" in the Remarks field of the claim and then the associated MAC adds a payer-only condition code of "ZC". With a two-step and manual process, there is likely some percentage of cases where the "ZC" code has not been applied as it should. CMS recently issued Transmittal 13043, which states that they will automate the application of the "ZC" code for cases that have both a clinical trial indicator and charges over $1.00 in revenue centers 0891 and/or 0892, beginning on July 7, 2025.[8] Assuming providers accurately record the "Diff Prod Clin Trial" for appropriate cases, this automatic processing should reduce the number of claims that meet the profile described by CMS.

CMS Response: ***Comment:*** *A commenter stated that a potential reason 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, is that the case involves a clinical trial of another product. The commenter stated that given the two-step and manual process in flagging these claims, (that is, the provider includes "Diff Prod Clin Trial" in the Remarks field and the MAC adds a payer-only condition code of "ZC"), there is likely a percentage of cases where the condition code was not applied as it should be. The commenter noted that CMS' recent billing instructions that automate the application of "ZC" should reduce the number of claims with this profile.*

Response: *We appreciate the feedback on our comment solicitation and will continue to monitor CAR T-cell therapy claims for such potential anomalies.* [FR 36654]

[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.
[8] CMS. SUBJECT: Fiscal Intermediary Shared System (FISS) Changes to Automate the Application of Condition Code ZC for Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapy Cases Involving a Clinical Trial of a Different Product, January 10, 2025. Online: https://www.cms.gov/files/document/r13043otn.pdf

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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 while some stakeholders may have the resources and expertise to review meeting materials, infer potential requested mappings for all therapies requesting new codes and submit mapping comments accordingly, many stakeholders will not. **If an applicant is requesting an MS-DRG mapping as part of the ICD-10-PCS process, this should be made explicitly public in the meeting materials, even if it is not discussed in the meeting itself.**

Additionally, CMS should not ask or expect all stakeholders to know enough about clinical care and CMS' mapping processes to be able to suggest an alternative mapping for a code, if required. In the case of ASTCT, we may have the expertise to identify when a new procedure code does not match the clinical homogeneity of MS-DRGs 014, 016-018, but we may not have the broader clinical expertise required to propose an alternative detailed mapping for products outside of our membership's core knowledge areas (hematological disorders and/or blood cancers). CMS has noted multiple times in prior year's rules that it relies upon a rigorous internal process to identify potential mappings, including the input of its medical advisors. ASTCT supports this and encourages CMS to continue with this approach and to specifically ask its medical advisors to pay special attention to MS-DRG mappings where stakeholders raise questions, including engaging in clinical discussions with external advisors, if needed.

ASTCT 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 also requests that CMS utilize its established processes to review and reconsider MS-DRG assignment when stakeholders raise concerns about CMS' assignment, instead of expecting stakeholders to propose alternative mappings.

CMS Response: ***Comment:*** *A commenter (the requestor) expressed appreciation for the clarification CMS provided regarding the submission of comments related to coding requests presented during the Spring ICD-10 Coordination and Maintenance Committee Meeting and that comments submitted after the Spring meeting will be shared with the groups responsible for considering MS-DRG mappings. The commenter stated that while some stakeholders may have the resources and expertise to review meeting materials, infer potential requested mappings for all therapies requesting new codes and submit mapping comments accordingly, many stakeholders will not. The commenter stated that if an applicant is requesting an MS-DRG mapping as part of the ICD- 10-PCS process, this should be made explicitly public in the meeting materials, even if it is not discussed in the meeting itself. The commenter also stated that CMS should not ask or expect all stakeholders to know enough about clinical care and CMS' mapping processes to be able to suggest an alternative mapping for a code, if required. The commenter reiterated its request for CMS to introduce a process by which stakeholders can review requested MS-DRG mappings as part of, or in parallel to, the ICD-10-PCS code request process. The commenter also requested that CMS utilize its established process to review and reconsider MS-DRG assignment when*

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stakeholders raise concerns about CMS' assignment instead of expecting stakeholders to propose alternative mappings.

Response: *We thank the commenter for the feedback. In response to the commenter's assertion that not all stakeholders may have the resources and expertise to review meeting materials, infer potential requested mappings for all therapies requesting new codes and submit mapping comments accordingly, we note that we have made all of the information and materials necessary to conduct those actions publicly available via the CMS website. Specifically, the ICD-10 Coordination and Maintenance Committee Meeting materials are available at: https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials, and the meeting process is summarized in the annual rulemakings available at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps. In addition, the ICD-10 MS-DRG Definitions Manual is made publicly available via the CMS website at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.*

In response to the commenter's statement that if an applicant is requesting an MS-DRG mapping as part of the ICD-10-PCS process it should be made public in the meeting materials even if it is not discussed in the meeting itself, we note that, as discussed in the preamble of the proposed rule (90 FR 18016) and this final rule, the purpose of the ICD-10 Coordination and Maintenance Committee meeting is to present code proposals based on requests received regarding coding updates (that is, additions, deletions, or revisions). Therefore, while mapping requests may be included in the submission of an ICD-10-PCS procedure code request, we disagree that the information should be included in the meeting materials. We underscore that the focus of the ICD-10 Coordination and Maintenance Committee meetings is on updates and maintenance to the ICD-10 code sets and not about how a potential new code may be designated or assigned under the IPPS, which is addressed through rulemaking. These are two separate and distinct processes, each with their own objectives and timelines.

In response to the commenter's statement that CMS should not ask or expect all stakeholders to know enough about clinical care and CMS' mapping processes to be able to suggest an alternative mapping for a code, if required, we note that under our established process, we consider requests for MS-DRG classification changes on an annual basis that are submitted via MEARIS™ at: https://mearis.cms.gov/public/home by the designated October 20 deadline for the upcoming fiscal year. If a proposal is subsequently put forth in rulemaking and members of the public submit comments expressing disagreement with that proposal (for example, proposed new MS-DRG(s), proposed reassignment of diagnosis and/or procedure codes, or their designation), the public comments routinely provide the rationale behind the disagreement as well as alternative suggestions) for our consideration, which we may be able to further evaluate. With respect to the mapping process, as discussed in the preamble of the proposed rule (90 FR 18016) and this final rule, under our established process, when a new procedure code is finalized, we review the predecessor code and MS-DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS-DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code. [FR 36557]

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Request for Rationale of 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. However, CMS only addressed some stakeholders' questions about recent mapping decisions, and did not discuss the remainder.

ASTCT asks CMS to discuss its rationale behind the mapping of Orca-T Allogeneic T-cell Immunotherapy 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.

CMS Response: ***Comment:*** *A commenter (the requestor) expressed appreciation that CMS shared the types of concerns and questions raised by stakeholders about the rationale for mapping new ICD-10-PCS codes for novel therapies into Pre-MDC MS-DRG 018; however, the commenter requested that CMS discuss the rationale for mapping Orca-T allogeneic T-cell immunotherapy to Pre-MDC MS-DRG 018.*

Response: *We thank the commenter for the feedback. The procedure code proposal for Orca-T allogeneic T-cell immunotherapy was discussed at the March 19-20, 2024 ICD-10 Coordination and Maintenance Committee meeting. We refer the reader to the meeting materials on the CMS website at: https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials for additional information regarding the request. ICD-10-PCS codes XW033BA (Introduction of Orca-T allogeneic T-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 10) and XW043BA (Introduction of Orca-T allogeneic T-cell immunotherapy into central vein, percutaneous approach, new technology group 10) became effective October 1, 2024, for FY 2025. Under our established process, we reviewed the predecessor code assignments. The predecessor codes for Orca-T allogeneic T-cell immunotherapy (hereafter referred to as Orca-T) are procedure codes 3E033GC (Introduction of other therapeutic substance into peripheral vein, percutaneous approach) and 3E043GC (Introduction of other therapeutic substance into central vein, percutaneous approach) that are designated as non-O.R. and do not affect MS-DRG assignment. We then reviewed other factors associated with Orca-T. Notably, Orca-T is a precision-engineered allogeneic stem cell and T-cell immunotherapy biologic (that is, a combination therapy comprised of immune cells, including regulatory T-cells (Tregs) and conventional T-cells (Tcons), and stem cells) that is in clinical trials and regulated under FDA section 351 of the Public Health Service Act (PHSA) as a biologic.*

Allogeneic hematopoietic stem cell transplant (alloHSCT) can provide a curative therapy for many patients with advanced hematologic malignancies. Unfortunately, despite advancements in identifying matching donors and medical care, patients can experience a variety of post-transplant complications including Graft Versus Host Disease (GvHD), infection and organ failure. GvHD is a condition in which the donated cells attack the recipient's tissues
which can lead to end organ damage.

Orca-T is derived from an HLA matched donor and combines progenitor stem cells along with highly purified T-cells in the form of regulatory T-cells (Tregs, a specialized CD4+ T cell subset) and conventional T-cells (Tcons). Because of its purified nature, the Tregs can proliferate and exist in a patient's tissues in a fashion not normally possible. While the stem cells serve to build a long term immune system in the

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recipient, the Tregs act to protect the patient's tissues and organs from GvHD and other toxicities. The Tcons component is designed to accelerate the reconstitution of a patient's immune system, mediating the graft-versus-leukemic effect, graft-versus-infection and the inflammatory responses, providing protection against infection.

Establishment of a successful allograft requires an approach that balances an enhancement of the graft-vs-tumor and graft-vs-infection effects while avoiding or limiting GvHD. While some immunotherapeutic agents treat an active disease process, the specialized cells in Orca-T are intended to immunologically mitigate significant post allograft complications such as GvHD and infection.

We note that both CAR T-cell therapy and Orca T-cell therapy are forms of immunotherapies that are indicated for patients diagnosed with acute lymphoblastic leukemia (ALL), among other types of cancer. One of the challenges experienced to date with the treatment of ALL is GvHD, which is what Orca-T is formulated to address. We also note that there are other procedure codes describing both allogeneic CAR T-cell and non-CAR T-cell immunotherapy currently assigned to MS-DRG 018. Therefore, we believe the assignment of Orca T-cell immunotherapy to Pre-MDC MS-DRG 018 is appropriate. [FR 36557]

Proposed Mapping of Valoctocogene Roxaparvovec to MS-DRG 018

ASTCT notes that- valoctocogene roxaparvovec is listed in Table 6B with a proposed mapping to MS-DRG 018, but CMS does not discuss any rationale for this proposal in the rule text. The title of MS-DRG 018 is Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies, and valoctocogene roxaparvovec is an off-the-shelf *in vivo* gene therapy that is *neither a CAR-T nor an immunotherapy*. Additionally, it does not require the same types of complex and specialized clinical resources to administer as the other therapies assigned to MS-DRG 018. As a result, and without any discussion or explanation from CMS about why its medical advisors have proposed this, ASTCT assumes that this assignment is simply based on the manufacturer's request to assign their product to MS-DRG 018 as part of the ICD-10-PCS code request application. It seems reasonable that the manufacturer might make this request solely based on the $2.9M price of the therapy and MS-DRG 018 having the highest relative weight.

However, CMS' acceptance of this requested mapping is concerning as it seems that resource homogeneity is the only factor being relied upon. ASTCT's understanding is that CMS has always discussed the importance of balancing both clinical and resource homogeneity when thinking about MS-DRG assignments for new therapies. As an example, CMS assigned several hematopoietic stem cell gene therapies to autologous transplant MS-DRGs (016 and 017) based on the clinical similiarity of the services being provided to the patient, rather than basing assignment on price point. If the latter had been deemed more critical at the time of those assignments, then CMS would have assigned these therapies to MS-DRG 018 as well. CMS also did not propose to map eladocagene exuparvovec to MS-DRG 018 after denying its request for a new MS-DRG (as discussed in subsequent section), though eladocagene exuparvovec has a similar price point. As mentioned previously, ASTCT cannot determine any consistent logic guiding the variation in recent mapping proposals and decisions.

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

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process and input from its clinical advisors to assign valoctogene roxaparvovec to a more clinically appropriate MS-DRG.

CMS Response: ***Comment:*** *A commenter stated that the procedure code describing valoctocogene roxaparvovec is listed in Table 6B in association with the proposed rule and a proposed mapping to Pre-MDC MS-DRG 018, but CMS did not discuss any rationale for this proposal in the rule text. The commenter stated that the title of Pre-MDC MS-DRG 018 is Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies, and valoctocogene roxaparvovec is an off-the-shelf in vivo gene therapy that is neither a CAR-T nor an immunotherapy. Additionally, according to the commenter, it does not require the same types of complex and specialized clinical resources to administer as the other therapies assigned to Pre-MDC MS-DRG 018. The commenter further stated that, as a result, and without any discussion or explanation from CMS about why its medical advisors have proposed this, they assume that this proposed assignment is simply based on the manufacturer's request to assign its product to Pre-MDC MS-DRG 018 as part of the ICD-10-PCS code request application. The commenter stated that CMS' acceptance of this requested mapping is concerning as it seems that resource homogeneity is the only factor being relied upon. The commenter stated its understanding is that CMS has always discussed the importance of balancing both clinical and resource homogeneity when considering MS-DRG assignments for new therapies. The commenter provided an example stating that CMS assigned several hematopoietic stem cell gene therapies to autologous transplant MS-DRGs 016 and 017 (Autologous Bone Marrow Transplant with CC/MCC and without CC/MCC, respectively) based on the clinical similarity of the services being provided to the patient, rather than basing assignment on price point. According to the commenter, if the latter had been deemed more critical at the time of those assignments, then CMS would have assigned the therapies to Pre-MDC MS-DRG 018 as well. The commenter also stated that CMS did not propose to map eladocagene exuparvovec to MS-DRG 018 after denying its request for a new MS-DRG (as discussed later in this section), though eladocagene exuparvovec has a similar price point. The commenter stated it cannot determine any consistent logic guiding the variation in recent mapping proposals and decisions.*

The commenter requested that CMS not finalize the proposed mapping of valoctocogene roxaparvovec to Pre-MDC MS-DRG 018 due to differences in clinical complexity and resource use. The commenter stated that CMS should use its established mapping process and input from its clinical advisors to assign valoctocogene roxaparvovec to a more clinically appropriate MS-DRG.

Response: *In response to the commenter's request that CMS not finalize the proposed mapping of valoctocogene roxaparvovec to Pre-MDC MS-DRG 018 because it 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 Pre-MDC MS-DRG 018, we note that, as discussed in prior rulemaking, consideration is given to the similarities and differences inresource utilization among patients in each MS-DRG and we strive to ensure that resource utilization is relatively consistent across patients in each MS-DRG. However, some variation in resource intensity will remain among the patients in each MS-DRG because the definition of the MS-DRG is not so specific that every patient is identical, rather the average pattern of resource intensity of a group of patients in an MS-DRG can be predicted. We note that historically, in the development of the DRGs, the initial step in the determination of the DRG had been the assignment of the appropriate MDC based on the principal diagnosis, however, beginning with the eighth version of the GROUPER (CMS 8.0), the initial step in DRG assignment was*

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based on the procedure being performed, thus the creation of the Pre-MDC DRGs, where the patient is assigned to these DRGs independent of the MDC of the principal diagnosis. Therefore, the logic for case assignment to Pre-MDC MS–DRG 018 does not preclude the assignment of other therapies indicated in the treatment of patients with different diagnoses. In our review of the MS-DRG assignment of valoctocogene roxaparvovec, we recognized that this technology is defined as a gene therapy. We also note that similar to the discussions in prior rulemaking with respect to the difficulty in predicting what the associated costs will be in the future for CAR T-cell and other immunotherapies that remain under development (87 FR 48806), it is also difficult to predict what the associated costs will be in the future for cell and gene therapies that remain under development or in clinical trials.

In response to the commenter's assertion that CMS did not use its established mapping process and input from its clinical advisors to assign valoctocogene roxaparvovec to a more clinically appropriate MS-DRG, as discussed in the preamble of the proposed rule (90 FR 18016) and this final rule, and as noted in prior rulemaking, we use our established process to examine the MS-DRG assignment for the predecessor codes to determine the most appropriate MS-DRG assignment. Specifically, we review the predecessor code and MS-DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS-DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. As noted previously and in prior rulemaking, this process does not automatically result in the new procedure code being assigned to the same MS-DRG or to have the same designation (O.R. versus Non-O.R.). We note that the proposal to create new procedure codes that describe the administration of valoctocogene roxaparvovec was discussed at the September 10, 2024 ICD-10 Coordination and Maintenance Committee meeting. The predecessor codes to describe the administration of valoctocogene roxaparvovec are ICD-10-PCS codes 3E033GC (Introduction of other therapeutic substance into peripheral vein, percutaneous approach) and 3E043GC (Introduction of other therapeutic substance into central vein, percutaneous approach) which are designated as non-O.R. and do not impact MS-DRG assignment. We refer the reader to the CMS website at: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials for additional detailed information regarding the code request, including a recording of the discussion and the related meeting materials. We also note that the procedure codes to describe the administration of valoctocogene roxaparvovec were approved and finalized as reflected in Table 6B. – New Procedure Codes associated with the proposed rule and this final rule (and available via the CMS website at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps) as well as reflected in the FY 2026 ICD-10-PCS code update files that were made publicly available on the CMS website on June 6, 2025 at: https://www.cms.gov/medicare/coding-billing/icd-10-codes. As discussed in section II.C.11. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule and this final rule, the code titles are adopted as part of the ICD-10 Coordination and Maintenance Committee meeting process that have been finalized after the review of public comments. As also discussed in the preamble of the proposed rule (90 FR 18067) and this final rule, we proposed the MDC and MS-DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes associated with the proposed rule. Therefore, the public has the opportunity to comment and provide feedback on the proposed assignments for CMS' consideration, which is subsequently included in the final rule with a summary of the comments and feedback and CMS' response, as is reflected in the discussion in this section of this final rule.

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In response to the commenter's statement that valoctocogene roxaparvovec does not require the same types of complex and specialized clinical resources to administer as other therapies assigned to Pre-MDC MS-DRG 018, we note that valoctocogene roxaparvovec is indicated in the treatment of Hemophilia A, an X-linked genetic disorder that results in a dysfunction in the gene encoding for Factor VIII which is essential for proper coagulation. Patients may have varying degrees of functional activity of Factor VIII with severe activity (<1IU per deciliter) resulting in spontaneous hemorrhage. This can result in life threatening hemorrhages into the brain or lead to debilitating hemorrhages in the soft tissues or joints leading to chronic pain or arthropathy. While prophylactic regimens may improve outcomes, they do not address the underlying dysfunctional gene encoding for Factor VIII. Valoctocogene roxaparvovec is a one-time therapy that uses an adeno-associated virus (AAV5) to deliver a functional copy of the F8 gene which is responsible for the production of Factor VIII. Valoctocogene roxaparvovec is similar to other gene based therapies currently assigned to Pre-MDC MS-DRG 18 such as prademagene zamikeracel (Zevaskyn™) and CAR T-cell therapy in that these treatments involve introduction of genetic material into a patient's cells to treat a disease process. CAR T-cell therapy uses a patient's genetically modified T-cells to treat cancer while prademagene zamikeracel and valoctocogene roxaparvovec introduce functional deoxyribonucleic acid (DNA) copies into a patient's skin and liver, respectively, to correct an inherited genetic dysfunction. While they are similar in character to the hematopoietic stem cell gene therapies assigned to autologous transplant MS-DRGs 016 and 017 (Autologous Bone Marrow Transplant with CC/MCC and without CC/MCC, respectively), resource utilization differs. Prademagene zamikeracel and valoctocogene roxaparvovec involve introduction of genetic material into mature cells while hematopoietic gene therapy involves introduction of genetic material into stem cells which require a level of resource utilization more akin to other therapies in MS-DRGs 016 and 017.

In response to the commenter's assumption that the manufacturer requested assignment to Pre-MDC MS-DRG 018 in association with its procedure code request, we note that it did not. We also take this opportunity to emphasize that, as has been discussed in prior rulemaking with respect to gene therapies, this category of therapies continues to evolve, and we are 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. We also note that valoctogene roxaparvovec is primarily administered in the outpatient setting (for example, hemophilia treatment centers). However, in rare instances when the therapy is administered in the inpatient setting or the patient must be transferred to the inpatient setting, providers are equipped with a specific procedure code to report its use in connection with a predictable payment mechanism under the IPPS. [FR 36558]

Discussion of New Neurosurgical Gene Therapy MS-DRG

Within the discussion of MS-DRG 018, CMS describes a stakeholder request to create a new MS-DRG for neurosurgical gene therapies. 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.[9]

[9] 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

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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 therapy) 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, CMS states that it did not find any cases with eladocagene exuparvovec in the FY 2024 MedPAR file. The ASTCT notes that this 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 is seeking from stakeholders.

CMS Response: ***Comment:*** *A commenter stated it is unclear why discussion of the request to create a new MS-DRG to describe neurosurgical gene therapies was included under the Pre-MDC MS-DRG 018 section of the proposed rule instead of under MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders) where prior discussions of eladocagene exuparvovec have been included. The commenter indicated that if CMS placed this discussion in the Pre-MDC MS-DRG 018 section in an effort to seek comments about whether Pre-MDC MS-DRG 018 should be broadened to include eladocagene exuparvovec and other gene therapies that it be made explicit what information the agency is seeking from stakeholders in advance of the FY 2027 IPPS/LTCH PPS rulemaking cycle. The commenter also stated that if CMS intends for Pre-MDC MS-DRG 018 to be the primary Pre-MDC MS-DRG for all cell and gene therapies until further modifications can be made, the agency should propose to rename the MS-DRG and be consistent with mapping practices and rationale. The commenter further remarked that CMS' proposed rule analysis stated no cases reporting eladocagene exuparvovec were found, however, according to the commenter, because the product was not approved until November 2024, cases would not be expected to appear in the data.*

Response: *As stated in the preamble of the proposed rule (90 FR 18016), in connection with the comments and questions about how products are grouped under the IPPS MS-DRGs, specifically with respect to cell and gene therapies under Pre-MDC MS-DRG 018, for FY 2026, we also received a request to create a new neurosurgical gene therapy MS-DRG, which we believe was appropriately placed and discussed in that section of the preamble of the proposed rule. As also explicitly stated in the preamble of the proposed rule (90 FR 18017), we continue to welcome additional feedback and comments on other*

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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options to consider on how to appropriately address low volume, high-cost treatments for rare diseases, therefore, we believe that our intentions were clearly stated. In response to the commenter's suggestion that a proposal to revise the title for Pre-MDC MS-DRG 018 should be put forth if CMS aims to temporarily designate Pre-MDC MS-DRG 018 as the primary Pre-MDC MS-DRG for all cell and gene therapies, we note that, as also stated in the preamble of the proposed rule, (90 FR 18016), there has been discussion related to requests to revise the title to Pre-MDC MS-DRG 018 in prior rulemaking, most recently in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69008 through 69010), and we continue to be interested in obtaining input from members of the public on options to consider, recognizing there are additional types of cell and gene therapies now mapping to Pre-MDC MS–DRG 018. We stated we will continue to review additional feedback and suggestions in connection with future rulemaking. In response to the commenter's remarks that CMS' proposed rule analysis stated no cases were found to report the administration of eladocagene exuparvovec and because the product was not approved until November 2024, cases would not be expected to appear in the data, we note that procedure code XW0Q316 (Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6) that describes the administration of eladocagene exuparvovec became effective October 1, 2020 (FY 2021) and a single case was previously identified in the data in MS-DRG 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with CC/MCC) with an average length of stay of 2 days and average costs of $1,544, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48854). We further note that, as also discussed in prior rulemaking, the creation of a code to describe a technology that is utilized in the performance of a procedure or service does not require FDA approval of the technology nor is the proposed and final assignment of a procedure code to an MS-DRG dependent upon a product's FDA approval (86 FR 44806).

Several commenters provided general feedback on the subject of cell and gene therapies for CMS' consideration in association with the Pre-MDC MS-DRG 018 proposed rule discussion. Notably, commenters suggested that CMS: (1) issue a Request for Information (RFI) to obtain additional insight on provider experiences, including information on the therapies under development and expected to become available in the near future, as well as features of their administration and the affected patient populations, (2) develop a payment model or long-term solution for appropriate payment that also accounts for products whose new technology add-on payment is expiring, and (3) ensure transparency in the refinement process by collaborating with stakeholders.

We appreciate the commenters' recommendations and feedback as we continue to examine the complexities involved with these therapies under the IPPS. We intend to address any potential modifications to the MS-DRGs through future notice and comment rulemaking. [FR 36560]

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:

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> *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).*[10]

A key reason for the high reliance on outlier payment for cases in MS-DRG 018 is that CMS' base payment is woefully inadequate, as evidenced by this MS-DRG where far more cases are reliant on outlier dollars than any other MS-DRG.

Providers do their best to heed CMS' guidance to set charges in accordance with their cost-to-charge ratios (CCRs)[11], which is necessary given CMS' NTAP and outlier formulas that rely on a calculated cost that CMS expects at minimum reflects product acquisition cost. While this guidance has been very useful and does result in more appropriate real-time provider payment for those who follow the guidance, the current process creates two key problems. First, providers heeding CMS' advice are often called out by the press and other stakeholders as having for high charges given the focus on drug pricing and price transparency.[12] Second, CMS' methodology understates the cost that CMS uses in future rate-setting. This is because CMS derives cost from billed charges using the national drug cost-to-charge ratio, which can vary significantly from hospital's own CCRs. This variance results in charge compression and an inadequate MS-DRG 018 payment rate – even as the highest paying MS-DRG in the system - which causes providers to rely disproportionately on outlier payment.

ASTCT has described its 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[13] and reiterates our concerns again here since it must be noted that the majority of cases in MS-DRG 018 receive substantial outlier dollars. 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*

[10] 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.
[11] 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.
[12] 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/.
[13] ASTCT, *ASTCT Policy Letters and Statements*, Chicago (IL): ASTCT, no date. Online: https://www.astct.org/Advocacy/Policy-Letters-and-Statements.

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> *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).*[14]

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 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.[15]

Within the proposed rule, 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).***[16]

CMS' calculation of an average case cost of $385,147 exemplifies the on-going issue of charge compression and the high-cost of immunotherapy products included in MS-DRG 018 for FY 2026. If the case costs for a hospital are reduced to a calculated cost of less than the product purchase price, this is a clear signal there are methodological issues with CMS' IPPS payment calculations that remain despite CMS' use of a unique rate-setting methodology.

ASTCT's analysis of the FY 2026 PR data shows that the base payment for MS-DRG 018 remains significantly out of alignment with true case costs:

- 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 exception even within the Pre-MDCs.

When CMS is not able to develop an adequate MS-DRG payment rate, the result is hospitals continuing to lose money due to a disproportionate number of cases assigned to the MS-DRG receiving outlier payments. We see this underpayment trend continuing year-over-year, despite providers heeding CMS'

[14] 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.
[15] ASTCT, *ASTCT Policy Letters and Statements*, Chicago (IL): ASTCT, no date. Online: https://www.astct.org/Advocacy/Policy-Letters-and-Statements.
[16] 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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guidance due to the significant charge compression that occurs. This problem will be exacerbated as CMS continues to map new therapies into MS-DRG 018 that have even higher acquisition costs – some that are up to four times the average cost of the majority of products in the MS-DRG today.

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

CMS Response: ***Comment:*** *A commenter stated that the MS-DRG payment for CAR T-cell therapy services has never been sufficient and provided various reasons for this, including problems with hospital chargemasters, CCRs, and charge compression. Commenters provided various suggestions to mitigate these concerns and increase the payment rate for MS-DRG 018. Commenters stated that the percentage of cases in MS-DRG 018 that are eligible for outlier payments has increased since FY 2021, which, the commenter stated, if left unaddressed, places a constraint on the outlier pool, which negatively impacts all hospitals. A commenter stated that hospitals should not be targeted for having high outlier payments given that it is the "new norm" for cell and gene therapies, and that hospitals should not be questioned if they set their charges consistent with their CCRs. This commenter stated that CMS needs to provide more clarity so that stakeholders understand that hospitals have no choice but to mark up product charges, and that patients do not bear the cost of those charges. This commenter also requested that CMS consider other methodologies to pay for immunotherapies and expand CMMI's cell and gene therapy model.*

Commenters requested that CMS explore the integration of Medicare Advantage claims into the ratesetting process for MS-DRG 018 to improve the sample size available for low volume products, which could improve the robustness and reliability of cost estimates. A commenter noted that as the percentage of enrollees in Medicare fee-for-service decreases, the number of claims used in the ratesetting process will decrease and become less representative for predicting resource utilization.

Response*: Regarding the comments that the MS–DRG relative weight for MS–DRG 018 is inadequate and does not result in payment that fully covers the hospital resource costs, as well as comments regarding hospital charging practices, we refer readers to the FY 2022 IPPS/LTCH final rule (86 FR 44965) where we responded to similar comments. With respect to the commenter's statement about hospitals being "targeted" for having high outlier payments, we are unaware of the issue the commenter is raising. We note our proposal, as discussed in the CY 2026 OPPS proposed rule (90 FR 33476), to collect payer-specific negotiated charge data from MA organizations by MS-DRG for use in the MS-DRG relative weight setting, would, if finalized, obviate many of the concerns that commenters raised, including challenges with hospital charging practices and the potential role of MA claims in the ratesetting process.* [FR 36655]

Accounting for Cell and Gene Therapies in the Cost Report

Given the rapid expansion of cell and gene therapy product approvals, ASTCT requests that CMS revise the cost reporting instructions to instruct providers to report cell and gene therapy product (i.e. biologics billed with the NUBC revenue code 0891 and 0892) expense and revenue only in cost center 78. ASTCT also requests that CMS revise the instructions to leave the services associated with these therapies in their original cost centers. ASTCT notes that there is precedent for CMS to define a cost

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center based on NUBC revenue codes, since it did so many years ago with the implantable device cost center. ASTCT strongly believes that having the cost of these products isolated into a unique cost center, and one that is still a type of drug cost center, will provide better data to CMS for future use.

Additionally, CMS' current instructions require providers to report their CAR-T service costs in cost center 78. To do this, providers must reclassify CAR-T collection and cell lab processing expense and revenue from the cost centers from which they typically accrue into cost center 78. ASTCT disagrees with this approach, since it creates unnecessary administrative burden for providers. Additionally, the results are likely to vary widely among hospitals, based on their differences in reclassification practices, which could result in incomplete and/or unreliable data in cost center 78.

ASTCT requests that CMS revise the cost report instructions to leave the services associated with cell and gene therapies in their original cost centers and requests that CMS clarify whether hospitals are allowed to use product charges and expenses as valid statistics to allocate administrative and general expense to cost report line 78.

CMS Response: ***Comment:*** *Commenters requested that CMS revise its cost reporting instructions for cell and gene therapy products (revenue codes 0891 and 0892) to instruct providers to use cost center 78. A commenter requested that CMS also instruct providers to leave the services associated with these therapies in their original cost centers. This commenter stated that there is a precedent for CMS to define a cost center based on a revenue code, like it did for the implantable devices cost center. The commenter also requested that CMS clarify whether hospitals are allowed to use product charges and expenses as valid statistics to allocate administrative and general expenses to cost report line 78.*

Response: *We do not believe changes to billing guidance are needed at this time but will take these comments into consideration when developing policies and program requirements for future years for CAR T-cell therapy policy. We further note that under the proposal in the CY 2026 OPPS proposed rule to collect payer-specific negotiated charge data from MA organizations by MS-DRG for use in the MS-DRG relative weight setting, an additional cost center would not impact the relative weight for MS-DRG 018.* [FR36655]

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."*[17]

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.[18] CMS responded with the following statement in the FY 2024 Final Rule:

[17] 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.
[18] 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.

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> *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.*[19]

Although further action was not taken in the FY 2025 PR, ASTCT is heartened that CMS proposes 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.*[20]

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 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 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.[21] Setting aside a very significant—and growing—percentage of cases each year from the rate-setting process 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.[22] CMS already has access to the data needed to examine the effect of MA

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[19] 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,.

[20] 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.

[21] 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.

[22] 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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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 volume and rate-setting. 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.

CMS Response: ***Comment:*** *. . . Commenters requested that CMS explore the integration of Medicare Advantage claims into the ratesetting process for MS-DRG 018 to improve the sample size available for low volume products, which could improve the robustness and reliability of cost estimates. A commenter noted that as the percentage of enrollees in Medicare fee-for-service decreases, the number of claims used in the ratesetting process will decrease and become less representative for predicting resource utilization.*

Response: *. . . We note our proposal, as discussed in the CY 2026 OPPS proposed rule (90 FR 33476), to collect payer-specific negotiated charge data from MA organizations by MS-DRG for use in the MS-DRG relative weight setting, would, if finalized, obviate many of the concerns that commenters raised, including challenges with hospital charging practices and the potential role of MA claims in the ratesetting process.* [FR 36655]

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

As raised in our earlier discussion of rationale for mapping products to MS-DRG 018, **ASTCT asks that CMS clarify the its rationale for mapping an allogeneic product delivered via stem cell transplant to MS-DRG 018.** Additionally, ASTCT remains very interested in meeting with CMS to discuss recent and expected future innovation in stem cell transplant.

CMS Response: ***Comment:*** *A commenter (the requestor) expressed appreciation that CMS shared the types of concerns and questions raised by stakeholders about the rationale for mapping new ICD-10-PCS codes for novel therapies into Pre-MDC MS-DRG 018; however, the commenter requested that CMS discuss the rationale for mapping Orca-T allogeneic T-cell immunotherapy to Pre-MDC MS-DRG 018.*

Response: *We thank the commenter for the feedback. The procedure code proposal for Orca-T allogeneic T-cell immunotherapy was discussed at the March 19-20, 2024 ICD-10 Coordination and Maintenance Committee meeting. We refer the reader to the meeting materials on the CMS website at: https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials for additional information regarding the request. ICD-10-PCS codes XW033BA (Introduction of Orca-T allogeneic T-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 10) and XW043BA (Introduction of Orca-T allogeneic T-cell immunotherapy into central vein, percutaneous approach, new technology group 10) became effective October 1, 2024, for FY 2025. Under our established process, we reviewed the predecessor code assignments. The predecessor codes for Orca-T allogeneic T-cell immunotherapy (hereafter referred to as Orca-T) are procedure codes 3E033GC (Introduction of other therapeutic substance into peripheral vein, percutaneous approach) and 3E043GC (Introduction of other therapeutic substance into central vein, percutaneous approach) that are designated as non-O.R. and do not affect MS-DRG assignment. We then reviewed other factors*

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associated with Orca-T. Notably, Orca-T is a precision-engineered allogeneic stem cell and T-cell immunotherapy biologic (that is, a combination therapy comprised of immune cells, including regulatory T-cells (Tregs) and conventional T-cells (Tcons), and stem cells) that is in clinical trials and regulated under FDA section 351 of the Public Health Service Act (PHSA) as a biologic.

Allogeneic hematopoietic stem cell transplant (alloHSCT) can provide a curative therapy for many patients with advanced hematologic malignancies. Unfortunately, despite advancements in identifying matching donors and medical care, patients can experience a variety of post-transplant complications including Graft Versus Host Disease (GvHD), infection and organ failure. GvHD is a condition in which the donated cells attack the recipient's tissues
which can lead to end organ damage.

Orca-T is derived from an HLA matched donor and combines progenitor stem cells along with highly purified T-cells in the form of regulatory T-cells (Tregs, a specialized CD4+ T cell subset) and conventional T-cells (Tcons). Because of its purified nature, the Tregs can proliferate and exist in a patient's tissues in a fashion not normally possible. While the stem cells serve to build a long term immune system in the recipient, the Tregs act to protect the patient's tissues and organs from GvHD and other toxicities. The Tcons component is designed to accelerate the reconstitution of a patient's immune system, mediating the graft-versus-leukemic effect, graft-versus-infection and the inflammatory responses, providing protection against infection.

Establishment of a successful allograft requires an approach that balances an enhancement of the graft-vs-tumor and graft-vs-infection effects while avoiding or limiting GvHD. While some immunotherapeutic agents treat an active disease process, the specialized cells in Orca-T are intended to immunologically mitigate significant post allograft complications such as GvHD and infection.

We note that both CAR T-cell therapy and Orca T-cell therapy are forms of immunotherapies that are indicated for patients diagnosed with acute lymphoblastic leukemia (ALL), among other types of cancer. One of the challenges experienced to date with the treatment of ALL is GvHD, which is what Orca-T is formulated to address. We also note that there are other procedure codes describing both allogeneic CAR T-cell and non-CAR T-cell immunotherapy currently assigned to MS-DRG 018. Therefore, we believe the assignment of Orca T-cell immunotherapy to Pre-MDC MS-DRG 018 is appropriate. [FR 36557]

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

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

As of FY 2025, there are multiple 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. 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 (SCD), as is expected to happen after the FY 2027 cycle. Without NTAP, hospitals will experience even greater losses than they currently do when providing these therapies under IPPS, given the tremendous portion of the case cost that will be paid through the

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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 that beneficiaries need.

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.*[23]

CMMI has made significant advancements with the CGT Access Model, recently indicating that 84% of Medicaid beneficiaries with SCD will be represented by the 35 states that elected to participate in the Model.[24] 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.*[25]

ASTCT asks CMS to reassess whether a mechanism can be established by which Medicare beneficiaries with SCD, particularly dual-eligible beneficiaries, can participate in the CMMI CGT model in order to ensure coverage for beneficiaries and adequate reimbursement for hospitals.

CMS Response: CMS did not respond to this request

Non-Monotonicity of MS-DRGs 016 and 017

CMS mentions MS-DRGs 016 and 017 in its discussion of non-monotonicity in a base MS-DRG, but the tables and relative weight files propose two different payment rates for these DRGs, however, indicating that non-monotonicity would not apply. Additionally, these MS-DRGs did not show in the list of MS-DRGs with non-monotonicity within the AOR/BOR file.[26]

ASTCT asks that CMS clarify whether non-monotonicity applies to MS-DRGs 016 & 017 for FY 2026.

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[23] CMS, *Acute Inpateint PPS*, Baltimore (MD), CMS, pages 75-77. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.
[24] CMS, *Cell and Gene Therapy (CGT) Access Model*, Baltimore (MD), CMS, no date. Online: https://www.cms.gov/priorities/innovation/innovation-models/cgt.
[25] 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
[26] 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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CMS Response: ***Comment:*** *A commenter requested that CMS clarify whether MS-DRGs 016 and 017 were non-monotonic***.**

Response: *The proposed rule inadvertently included an incorrect list of MS-DRGs where a calculation was applied to address non-monotonicity. This list should have been MS-DRG 095 and MS-DRG 096, MS-DRG 217 and MS-DRG 218. After consideration of the comments received, we are finalizing our proposals without modifications related to the recalibration of the FY 2026 relative weights.* [FR 36652]

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

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