ASTCT
American Society for
Transplantation and Cellular Therapy

This document contains submitted ASTCT comments and selections from CMS' responses in the FY 2025 IPPS Final Rule, dated August 1, 2024. The Executive Summary has been removed from this version.

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

June 3, 2024

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: CMS-1808-P: Medicare and Medicaid Programs and the Children's Health Insurance 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 2025 Rates; Quality Programs Requirements; and Other Policy Changes

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit the following comment letter regarding the FY 2025 IPPS Proposed Rule, focusing on MS-DRGs of primary interest to ASTCT members.

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.

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

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This document contains submitted ASTCT comments and selections from CMS' responses in the FY 2025 IPPS Final Rule, dated August 1, 2024.

Fixed-Loss Threshold

ASTCT members have expressed very strong concerns about CMS' proposal to increase the fixed-loss threshold for FY 2025 to $49,237. The proposed amount equates to a 15% increase from the FY 2024 amount and is ***more than double*** the amount of $23,570 from FY 2017. The outlier payment formula forces a 20% loss by design, since Medicare only pays 80% of the residual calculated cost. Coupled with a growing fixed-loss threshold of more than $49,000 for each case, these losses are of significant financial concern. A recent report from the American Hospital Association (AHA) calculated that Medicare pays hospitals approximately 82 cents on the dollar.[1] Given this reality, if the upward trend in the fixed-loss threshold continues at the same rate in future years and there is no corresponding increase in base MS-DRG payment rates, hospitals will face even greater financial duress.

Our members are deeply concerned with the rise in the fixed-loss threshold because of the cell therapy (MS-DRG 018) and stem cell transplant (MS-DRG 016 and 017) cases that typically generate significant outlier dollars. They are also concerned by the impact to all other DRGs, including DRGs within MDC 17 – Myeloproliferative Diseases and Disorders, which are high-volume and encompass many of the treatments for leukemia and lymphoma.

While CMS discusses some of the reasons for the rise in the fixed-loss threshold (infectious disease, etc.), we also know that 66% of FY 2023 MS-DRG 018 cases received outlier payments. This large percentage of MS-DRG 018 cases receiving outlier payment indicates that the base payment is insufficient. It also underscores the point that ASTCT has been raising for several years: that systematic charge compression issues associated with the development of the base payment is very problematic for cases involving high-cost cell and gene therapy products.

ASTCT requests that CMS carefully study how to slow the growth in the fixed-loss threshold. Additionally, ASTCT requests that CMS implement our recommendation that the agency use the "other" cost-to-charge ratio (CCR) for cell and gene therapy products as one strategy to address the fixed-loss threshold's rapid growth (see MS-DRG 018 section).

CMS Response: CMS did not respond to this request and finalized an outlier threshold of $46,152.

New Technology Add-on Payment (NTAP)

NTAP payment of 75% will not create access to gene therapies

On December 8, 2023, the United States Food and Drug Administration (FDA) approved two gene therapies for use in SCD: exagamglogene autotemcel (exa-cel; Casgevy™, also approved for transfusion-dependent beta thalassemia [TDT]) with a list price of $2.2 million; and lovotibeglogene autotemcel

[1] American Hospital Association. Medicare Significantly Underpays Hospitals for Cost of Patient Care. January 2024. Online: https://www.aha.org/system/files/media/file/2024/01/medicare-significantly-underpays-hospitals-for-cost-of-patient-care-infographic.pdf

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(lovo-cel; Lyfgenia™) with a list price of $3.1 million.[2,3] Betibeglogene autotemcel (beti-cel; Zynteglo™), another HSC gene therapy, was approved for use in TDT patients on August 17, 2022.[4]

ASTCT's members include physicians and hospitals that were intimately involved in the clinical development of these therapies and caring for the clinical trial patients who made these approvals possible. Our members are eager to provide these HSC gene therapies to the individuals and families who have been anxiously awaiting their turn for a functional cure. ASTCT members are frustrated and confused as to why the NTAP proposal and the Centers for Medicaid & Medicare Innovation's (CMMI) new Cell and Gene Therapy (CGT) Access Model only apply to SCD. The approved therapies for TDT also have the same pricing and access concerns as SCD and many of the waiting patients also have no other curative alternatives. We focus our comments in this letter primarily on SCD for purposes of simplicity but ask CMS to reconsider the its proposals to include TDT.

In response to the FDA approvals, CMMI announced that it would focus the efforts of its new CGT Access Model on these same gene therapies. CMMI stated that the Model *"aims to improve the lives of people with Medicaid living with rare and severe diseases by increasing access to potentially transformative treatment."*[5] While the Model still needs to be operationalized and evaluated for health system impact, its unique methodology is both unprecedented and highly justified, given the significant health burden and lack of therapeutic options for people living with severe SCD.

In stark contrast to the extensive CMMI Model, CMS makes only one policy proposal for the SCD therapies in the FY 2025 IPPS Proposed Rule. CMS proposes to increase the standard NTAP maximum amount from 65% to 75%, which effectively provides very few additional dollars due to NTAP methodology. The agency did not discuss its evaluation of any other solutions for improving the overall MS-DRG payment system, nor propose any other solutions for the HSC gene therapies, despite stakeholders having provided many ideas in the past. Moreover, CMS risks creating a two-tier system by fostering innovation for Medicaid patients via CMMI while offering no solutions for traditional Medicare Fee-for-Service (FFS) or Medicaid-Medicare dual-eligible patients with SCD or TDT.

ASTCT stresses that the lack of significant payment proposals related to the HSC gene therapies will result in severe limitations of access to care for Medicare beneficiaries with SCD and TDT.

ASTCT also acknowledges that the prices of HSC gene therapies are beyond what was imagined when the IPPS system was designed; they are also beyond the control of the provider community. ASTCT acknowledges the challenges facing CMS in an era of rapid medical innovation, rising costs, and growing numbers of beneficiaries.

We express our genuine appreciation for the partnership CMS has shown in the development and evolution of MS-DRG 018. Specifically, CMS listened to stakeholder input, recognized limitations of its existing payment system, and ultimately implemented not only an increase in the NTAP percentage but also improved payment and rate-setting methodologies to better accommodate the scientific innovation that CAR-T represents. When ASTCT flagged this issue in last year's comment letter and asked CMS to engage stakeholders in developing a solution proactively, ASTCT recognized that CMS was unlikely to

[2] US FDA. "FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease", December 8, 2023: https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease
[3] Reuters. "Vertex/CRISPR price sickle cell disease gene therapy at $2.2 mln", December 8, 2023: https://www.reuters.com/business/healthcare-pharmaceuticals/vertexcrispr-price-sickle-cell-disease-gene-therapy-22-mln-2023-12-08/
[4] US FDA. Zynteglo. Accessed May 28, 2024. Online: https://www.fda.gov/vaccines-blood-biologics/zynteglo
[5] CMS.gov. Cell and Gene Therapy Access Model. https://www.cms.gov/priorities/innovation/innovation-models/cgt

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propose significant MS-DRG or IPPS changes prior to FDA approval of HSC gene therapies. The lack of substantial payment proposals in this year's PR, however—despite having months of lead time due to the December 2023 approval—is extremely frustrating for our membership.

The NTAP increase that CMS proposes does not address the series of ***compounding losses for hospitals that wish to provide these therapies****: a low base MS-DRG payment rate, an inadequate NTAP percentage, the highest-ever fixed-loss threshold, and recovery of only 80% of remaining calculated costs through the outlier formula.*

These losses directly obstruct Medicare patients' access to gene therapies because the absolute dollars lost at each juncture of the stacking payment methodology is cumulatively untenable. It is unacceptable for hospitals to have to choose between not providing these therapies or bearing enormous losses to do right by their patients.

ASTCT requests that CMS implement the following in the FY 2025 IPPS Final Rule:

- **Modify the NTAP proposal from 75% of the product cost to a 100% cost-based reimbursement methodology using NTAP dollars during the 2-3 year period that NTAP would be in place.**
- **Expand the proposal's limited focus and include TDT patients, given that the pricing and access issues are the same.**
- **Require Medicare Administrative Contractors (MACs) to issue documentation confirming that these therapies will be covered per the FDA label.**
- **Do not make NTAP status for these therapies contingent on their participation in other pricing arrangements for the FY 2025 IPPS cycle.**

If implemented, ASTCT's proposed solution would enable CMS to side-step the current methodological challenges and promote access. In the meantime, the agency can work with stakeholders to develop a more sustainable long-term payment structure for cell and gene therapies for which the product costs outweigh the patient care portion of the MS-DRG tenfold.

Now that the predicted extreme prices are a reality, ASTCT implores CMS to put forth a solution that holds providers harmless and enables patients to access needed care from clinicians and hospitals that want to provide it. This temporary solution is necessary to create parity with CMMI's innovative work and to generate better data for future rate-setting. We describe our methodological recommendations and the rationale in greater detail in the following sections.

CMS Response:

CMS Response – Casgevy NTAP application: *After consideration of the public comments and the information included in the applicant's new technology add-on payment application, we have determined that Casgevy™ for the indication of SCD meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for SCD for FY 2025. Cases involving the use of Casgevy™ for the indication of SCD that are eligible for new technology add-on payments will be identified by ICD-10-PCS codes: XW133J8 (Transfusion of exagamglogene autotemcel into peripheral vein, percutaneous approach, new technology group 8) or XW143J8 (Transfusion of exagamglogene autotemcel into central vein, percutaneous approach, new technology group 8) in combination with one of the following ICD-10-CM codes: D57.1 (Sickle-cell*

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disease without crisis), D57.20 (Sickle-cell/Hb-C disease without crisis), D57.40 (Sickle-cell thalassemia without crisis), D57.42 (Sickle-cell thalassemia beta zero without crisis), D57.44 (Sickle-cell thalassemia beta plus without crisis), or D57.80 (Other sickle-cell disorders without crisis).

In its application, the applicant estimated that the cost of Casgevy™ is $2,200,000 per patient. As discussed in section II.E.10 of the preamble of this final rule, we are revising the maximum new technology add-on payment percentage to 75 percent, for a medical product that is a gene therapy that is indicated and used specifically for the treatment of SCD and approved for new technology add-on payments for the treatment of SCD in the FY 2025 IPPS/LTCH PPS final rule. Accordingly, under § 412.88(a)(2) as revised in this final rule, we limit new technology add-on payments to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of Casgevy™ for the treatment of SCD is $1,650,000 for FY 2025.

For full discussion, see pp. 385-388

CMS Response – Lyfgenia™ NTAP application: *After consideration of the public comments received, and the information included in the applicant's new technology add-on payment application, we have determined that Lyfgenia™ meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2025. Cases involving the use of Lyfgenia™ that are eligible for new technology add-on payments will be identified by ICD-10- PCS codes: XW133H9 (Transfusion of lovotibeglogene autotemcel into central vein, percutaneous approach, new technology group 9) or XW143H9 (Transfusion of lovotibeglogene autotemcel into peripheral vein, percutaneous approach, new technology group 9).*

In its application, the applicant estimated that the cost of Lyfgenia™ is $3,100,000 per patient. As discussed in section II.E.10. of the preamble of this final rule, we are revising the maximum new technology add-on payment percentage to 75 percent, for a medical product that is a gene therapy that is indicated and used specifically for the treatment of SCD and approved for new technology add-on payments for the treatment of SCD in the FY 2025 IPPS/LTCH PPS final rule. Accordingly, under § 412.88(a)(2) as revised in this final rule, we limit new technology add-on payments to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of Lyfgenia™ for the treatment of SCD is $2,325,000 for FY 2025.

For full discussion, see pp. 525-527

CMS Response – Substantial Similarity: *We thank the applicant and the other commenters for their comments. Based on our review of comments received and information submitted by the applicant as part of its FY 2025 new technology add-on payment application for Casgevy™, we agree that Casgevy™ and Lyfgenia™ do not have the same mechanism of action because Casgevy™ modifies a patients' own HSPCs to increase HbF expression to subsequently reduce the expression of intracellular sickled hemoglobin concentration, which is a distinct mechanism of action compared to Lyfgenia™, which modifies a patients' own HSPCs to increase HbAT87Q (modified adult hemoglobin). Therefore, we agree with the applicant that Casgevy™ has a unique mechanism of action and is not substantially similar to existing treatment options for the treatment of SCD in patients 12 years of age or older with recurrent VOCs and meets the newness criterion. We consider the beginning of the newness period for Casgevy™ to commence on December 8, 2023, when Casgevy™ was granted BLA approval from FDA for the treatment of SCD in patients 12 years of age or older with recurrent VOCs.*

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For full discussion of the described differences between technologies, see pp. 372-376

ASTCT's Proposed Cost-Based NTAP Methodology

ASTCT requests that CMS utilize NTAP dollars to reimburse hospitals for 100% of their product acquisition costs related to the provision of HSC gene therapies for SCD and TDT. This can be done by exercising CMS' equitable adjustment authority, if necessary, under Section 1886(d)(5)(I) of the Social Security Act. This Section allows CMS to "provide by regulation for such other exceptions and adjustments to such payment amounts under [IPPS] as the Secretary deems appropriate."

CMS can use the following methodology to operationalize our request:

- Require hospitals to use value code 90 to report the product acquisition cost.
- Provide separate payment for the individual HSC gene therapy at 100% of the reported product cost using NTAP dollars rather than utilizing the traditional formula to determine NTAP payment.
- When calculating total case payment—and specifically in determining whether an outlier payment is warranted—CMS can remove the charges reported in revenue code 0892 so the HSC gene therapy product charge is not utilized in the outlier formula. As a result, any outlier payment made would be for patient care costs that exceed CMS' base payment plus the fixed-loss outlier threshold.

By implementing ASTCT's recommended methodology, CMS would only reimburse the hospitals' product acquisition price and hospitals would still be incentivized to provide cost-effective care, as the MS-DRG payment and outlier calculations would still be applicable to the clinical care portion of the claim.

CMS Response:

Focus on Sickle Cell Disease: *Most of the commenters supporting the policy stated that they believed CMS should finalize as proposed, and also requested that CMS extend the policy further in various ways, while some stated they would support the proposal with varied modifications. Many of the commenters requested that CMS expand or modify the proposal to increase the add-on percentage to other therapies in addition to gene therapies treating SCD, stating that increasing the percentage allows for hospital adoption of groundbreaking therapies and advances the new technology add-on payment program's objective for expanding patient access to innovative new technologies. A commenter stated that while the focus on SCD is commendable, the narrow application of the proposal to specific therapies, and potentially only those engaged in valuebased purchasing agreements, indicates a limited scope of financial support. (p. 651)*

A few commenters requested that CMS extend the 75 percent to therapies with regenerative medicine advanced therapy (RMAT) or Breakthrough Therapy designations; to those targeting rare diseases, unmet needs, or vulnerable groups; or to other transformative therapies that Medicare beneficiaries may have difficulty accessing. Some commenters requested that CMS extend an increased new technology add-on payment percentage to align with other Administration priorities, such as hospital preterm deliveries, very low birth weight babies, other critically ill pediatric patients, and maternal health technologies. A commenter requested that CMS extend the increased maximum percentage to transformative therapies as opportunities arise, and that CMS monitor when additional increases higher than 75 percent are warranted.

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Some of the commenters stated that all cell and gene therapies should receive the increase to 75 percent, stating that CMS's stated reasons for the proposal apply to these therapies as well, and that cell and gene therapies may pose similar beneficiary access challenges based on inadequate payment. Commenters cited as their rationales that these therapies are generally treating small patient populations, rare disease, certain cancers, underserved populations, and/or orphan indications with significant unmet medical need. A commenter explained that cell and gene therapies often require complex manufacturing processes, specialized infrastructure, and intensive monitoring, and that these costs are embedded in the cost of these products, making them more costly. The commenter added that these therapies often have no historical claims data to characterize resource use associated with the inpatient admissions since patients may not even have been admitted previously due to a lack of treatment options (as compared to other types of new technology add-on payment technologies that represent improvements on or alternatives to existing treatments), and that therefore new technology add-on payment is needed to compensate for the absence of any costs from the rate setting methodology. Another commenter added that cell and gene therapies cause a significant strain on hospital financial resources; even with a new technology add-on payment, these therapies are more likely than other inpatient stays to qualify for outlier payments. A commenter stated that there is a need to incentivize newly approved high-cost, high-reward cellular and gene therapies through new technology add-on payment as there continues to be insufficient inpatient reimbursement for autologous cellular therapies, like CAR T-cell therapies. Commenters stated that inpatient stays with cell and gene thera pies, like CAR T-cell therapies. Commenters stated that inpatient stays with cell and gene therapies are inadequately paid, even with new technology add-on payments, which could dissuade hospitals from providing these therapies. A commenter specified further that particularly cell and gene therapies that treat other inherited, debilitating, and under-treated conditions like hemophilia and Duchenne muscular dystrophy (DMD) should receive this increase, stating that the significant costs and limited therapies to treat these patients justify an increase above other new technology add-on payment applicants. Commenters also requested that therapies that share characteristics with gene therapies for SCD should be included in the proposal, including the significant upfront costs to hospitals and significant reduction in chronic care needs and costs to the Medicare program on an ongoing basis. A commenter stated that reductions in chronic care costs accrue to Medicare rather than providers, and new technology add-on payment is a pathway to bridge the gap by providing support for hospitals that incur the up-front cost of purchasing these therapies. Another commenter also stated that increasing the new technology add-on payment percentage for cell and gene therapies would, in addition to supporting Medicare beneficiary access to these therapies, be beneficial to Medicaid patients as many are dually eligible. (p. 653-654)

Several commenters requested that CMS expand its proposal to include transfusion-dependent beta thalassemia (TDT). Commenters questioned why this proposal from CMS only applied to gene therapies for SCD and did not include FDA-approved gene therapies for TDT, which have the same public policy, pricing, and access concerns as SCD, and also have no curative alternatives. A commenter further stated that like SCD, historical treatment options for TDT also carry numerous limitations resulting in significantly under-served patient populations. The commenter also stated that extending enhanced new technology add-on payment to gene therapies used for TDT would be likely to have a minimal impact to the IPPS from a budget neutrality perspective because there was only an estimated 1,000 to 1,500 individuals in the U.S. living with TDT, with a far smaller proportion of Medicare-eligible individuals. (p. 654)

***Response:** We appreciate the commenters' feedback. We thank commenters for their support of the proposal. We continue to believe that the policy aligns with the Administrationidentified commitment to improving outcomes for patients with SCD by facilitating access to gene therapies that treat SCD,186 and*

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also balances the need to maintain the incentives inherent to the prospective payment system. With regard to commenters requesting that the proposal include different groups of therapies or those with particular designations, or all therapies approved for new technology addon payment, we recognize that the goal of facilitating access to new technologies for Medicare beneficiaries could also apply to other types of therapies. However, as discussed in the proposed rule (89 FR 36138), we focused our proposal on gene therapies for Medicare beneficiaries with SCD, as the most common inherited blood disorder, with historically limited treatment options and a significant clinical and financial impact on the healthcare system, and consistent with the Administration's commitment to improving outcomes for patients with SCD by facilitating access to gene therapies that treat SCD. We appreciate commenters' interest in improving access to these and other technologies through the new technology add-on payment program, and will continue to consider the interest areas raised by commenters.

With respect to comments that stated hospitals receive millions in outlier payments on the same cases that receive new technology add-on payment payments, highlighting how inadequate the new technology add-on payment is, and that even with a new technology add-on payment, cell and gene therapies are more likely than other inpatient stays to qualify for outlier payments, we disagree that the existence of outlier payments for some new technology cases is evidence that those payments are necessarily inadequate, as there may be unrelated reasons why a hospital would receive outlier payments. There may also be circumstances where new technology payments and outlier payments work in a complementary manner for related reasons, that do not necessarily mean the appropriate policy is to increase new technology payments.

Increase beyond 75%: ***Comment:*** *Some of the commenters requested that CMS modify its proposal and finalize a maximum payment higher than 75 percent, stating that an increase of 10 percent would not 186 Biden-Harris Administration Announces Action to Increase Access to Sickle Cell Disease Treatments https://www.hhs.gov/about/news/2024/01/30/biden-harris-administration-announces-action-increase-access-sicklecell-disease-treatments.html adequately address the underlying problem of insufficient reimbursement. Many of these commenters stated that, considering the transformational potential of these therapies and the fact that these are among the costliest treatments to date, CMS should increase the percentage to 100 percent to provide a better incentive for hospitals to provide these therapies and not impede access for Medicare beneficiaries. Commenters stated that this is important since hospitals already incur losses on treatments that trigger new technology add-on payments, and these SCD therapies are even more costly. A commenter stated that in the absence of any other evaluation or discussion of reimbursement solutions, hospitals will be left to bear enormous losses for an essential therapy where there are no alternatives with similar outcomes, which would directly obstruct Medicare patients' access to gene therapies based on prices that are beyond the control of the provider and hinder future treatment options for this patient population. In addition, a commenter stated that Medicare payment policy sets the standard for other payers, so there would be a downstream effect of limited access if the policy is finalized as proposed at 75 percent. The commenter further stated that if these SCD therapies are not provided due to inadequate new technology add-on payment, there will be no data available to set appropriate rates after the new technology add-on payment period expires that include the costs of the therapies and associated inpatient costs. Another commenter stated that anything less than 100 percent would be inadequate due to significant financial losses that would need to be absorbed on every case, particularly for high DSH hospitals, which many hospitals that treat SCD are likely to be. The commenters stated that a payment rate of 100 percent would allow CMS to most effectively incentivize the development of important new technologies like gene therapies, help ensure patient access, reduce health disparities, positively impact other payer coverage decisions, and appropriately recognize the durable and transformative value that gene therapies offer to patients, their families, and society. A commenter stated that a 100 percent payment rate would demonstrate the same commitment to equity in*

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the Medicare FFS population that the Cell and Gene Therapy (CGT) Access Model demonstrates for the Medicaid population. The commenter stated that 100 percent is reasonable given that the costs may be lower than anticipated due to the limited number of patients who may be candidates for SCD gene therapy and the limited manufacturing capacity, which is estimated to be less than 200 treatments per year.

Another commenter stated that anything short of 100 percent reimbursement of acquisition costs would be inadequate for cell and gene therapies while eligible for new technology add-on payment. The commenter stated that increasing the payment to the full cost amount would ensure health equity and access. Another commenter suggested that CMS fully cover the costs of SCD gene therapy either by increasing the payment rate or through another innovative approach such as developing a new DRG with a higher base payment. A commenter also suggested that as an alternative to 100 percent payment, CMS should negotiate drug prices directly with drug manufacturers, or alternative pathways to support coverage and access. Another commenter advocated for a policy solution that would ensure providers recoup at least the invoice cost of high-cost therapies such as Casgevy™ and Lyfgenia™, as the invoice cost of drugs is a factor over which providers have no control.

Response: *We appreciate the commenters' feedback. With regard to the comments requesting an increase to the new technology add-on payment percentage above the proposed rate of 75 percent, we acknowledge that SCD gene therapies are among the costliest therapies to date and there may be significant related costs associated with inpatient stays during which the therapies are provided. We also recognize that new technology add-on payment would not fully cover a hospital's costs, even with a 100 percent payment rate, due to the inherent design of the IPPS. At the same time, we note that we remain concerned about the extremely high cost of these products, and want to ensure we do not create incentives to increase prices. We continue to believe that limiting the new technology addon payment percentage provides hospitals an incentive for continued cost-effective behavior in relation to the overall costs of the case. In response to commenters requesting a new technology add-on payment percentage of 100 percent, we believe that this would result in very little of the incentive for cost-effective behavior inherent to the prospective payment system. While we continue to believe that our standard add-on payment percentage is generally appropriate, due to the particular concerns related to SCD gene therapies previously discussed and confirmed by comments and consistent with the Administration's commitment to improving outcomes for patients with SCD by facilitating access to gene therapies that treat SCD, at this time we believe it is appropriate to apply a higher new technology add-on payment of 75 percent for SCD gene therapies approved for new technology add-on payment for FY 2025 during their new technology add-on payment period. We believe that the proposed 75 percent payment rate would reasonably address these concerns while also maintaining the incentives inherent to the prospective payment system, and it is consistent with our new technology add-on payment policy for QIDPs and LPADs. For these reasons, we are finalizing the increase in the new technology add-on payment percentage for cell and gene therapies that treat SCD as proposed.*

With respect to commenters' other requested changes to our current payment mechanisms, due to the relative newness of these gene therapies for SCD and our continued consideration of approaches and authorities to encourage value-based care and lower prices of costly therapies, we believe it would be premature to adopt further structural changes to our existing payment mechanism specifically for these therapies. For these reasons, we disagree with the commenters' requested changes to our current payment mechanisms for FY 2025. For these same reasons, we also believe it would be premature to adopt a permanent increase in the new technology add-on payment percentage at this time. We will consider these comments should we develop additional policies and consider longer-term solutions related to SCD gene therapies in the future as we gain more experience with the unique considerations of

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these therapies. We also note that while Medicare payment policy may set the standard for other payers, payers consider many factors in designing and operating their programs. (p.655-660)
For full discussion, see pp. 646-660

Rationale to utilize NTAP dollars for product cost reimbursement

Health equity and access for all patients

ASTCT's methodological recommendations align with the Biden-Harris Administration's focus on health equity and CMS' stated intent to support access and incentivize cost-effective clinical care. CMS requires that any therapy available to non-Medicare beneficiaries must also be made available to Medicare beneficiaries—and vice versa.

Specifically, the Medicare provider agreement states the following:

> *In the agreement between CMS and a provider, the provider agrees to accept Medicare beneficiaries for care and treatment. The provider cannot impose any limitations with respect to care and treatment of Medicare beneficiaries that it does not also impose on all other persons seeking care and treatment. If the provider does not furnish treatment for certain illnesses and conditions to patients who are not Medicare beneficiaries, it need not furnish such treatment to Medicare beneficiaries in order to participate in the Medicare program. It may not, however, refuse to furnish treatment for certain illnesses or conditions to Medicare beneficiaries if it furnishes such treatment to others. Failure to abide by this rule is a cause for termination of the provider's agreement to participate in the Medicare program (see the regulations at 42 CFR 489.53(a)(2), and also see Pub. 100-01, Medicare General Information, Eligibility, and Entitlement Manual, chapter 5, §10.2).*[6]

Thus, if hospitals determine that it is not financially feasible to provide these therapies to Medicare beneficiaries, they might restrict use across all payer types (and thus, all patients) in order not to violate CMS' regulations. If CMS fails to find a way to make the provision of these therapies to inpatients fiscally possible, access for *all* patient populations could be threatened.

Significant disparities between CMS' Medicaid and Medicare proposals

By CMS' own estimates, there were 11,790 Medicare beneficiaries with SCD in 2016, more than 70% of whom were dual-eligible, and the majority of whom were non-elderly.[7] While the current total number of Medicare beneficiaries with SCD is unknown, one can reasonably assume there are Medicare beneficiaries who are interested in and eligible for these therapies.

Access is a critical issue, given how important these therapies are for a patient population that is in extreme need of options. As the FDA noted in its approval of the therapies:

[6] CMS. Medicare Claims Processing Manual, Chapter 1, Section 30.1.3: Provider Treatment of Beneficiaries. Accessed: May 16, 2024. Online: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c01.pdf
[7] Wilson-Frederick, SM. CMS Office of Minority Health. Prevalence of Sickle Cell Disease among Medicare Fee-for-Service Beneficiaries, Age 18-75 Years, in 2016. Online: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-15-Sickle-Cell-Disease.pdf

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> *Sickle cell disease is a rare, debilitating and life-threatening blood disorder with significant unmet need, and we are excited to advance the field especially for individuals whose lives have been severely disrupted by the disease by approving two cell-based gene therapies today," said Nicole Verdun, M.D., director of the Office of Therapeutic Products within the FDA's Center for Biologics Evaluation and Research. "Gene therapy holds the promise of delivering more targeted and effective treatments, especially for individuals with rare diseases where the current treatment options are limited.*
>
> *These approvals represent an important medical advance with the use of innovative cell-based gene therapies to target potentially devastating diseases and improve public health," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "Today's actions follow rigorous evaluations of the scientific and clinical data needed to support approval, reflecting the FDA's commitment to facilitating development of safe and effective treatments for conditions with severe impacts on human health.*[8]

ASTCT agrees that these are groundbreaking therapies. We were pleased to see a subsequent press release from the Department of Health & Human Services (HHS) leadership on this issue. The CMMI's CGT Access Model echoes the importance of making these therapies accessible to the individuals who need them and confirms HHS' commitment to supporting their availability. The HHS press release announcing the new Model stated:

> *Gene therapies for sickle cell disease have the potential to treat this devastating condition and transform people's lives, offering them a chance to live healthier and potentially avoid associated health issues," said CMS Administrator Chiquita Brooks-LaSure. "Increasing access to these promising therapies will not only help keep people healthy, but it can also lead to savings for states and taxpayers as the long-term costs of treating sickle cell disease may be avoided.*[9]

This statement is true of all government program beneficiaries and reinforces why it is so disappointing that the CGT Model *only* applies to Medicaid beneficiaries and does nothing to expand care for Medicare-only and Medicaid-Medicare dual-eligible individuals. 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.*[10]

ASTCT does not view CMS' FY 2025 IPPS proposal to slightly increase NTAP as being in harmony with the level of attention and effort being put into the CMMI model. FFS Medicare and dual-eligible beneficiaries with SCD and TDT deserve a focus and level of effort equivalent to that being advanced for the Medicaid population through the CMMI Model.

[8] U.S. Food and Drug Administration. Press Release: FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease Online: https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease
[9] CMS Newsroom. Biden-Harris Administration Announces Action to Increase Access to Sickle Cell Disease Treatments. January 30, 2024, Online: https://www.cms.gov/newsroom/press-releases/biden-harris-administration-announces-action-increase-access-sickle-cell-disease-treatments
[10] CMS. Transcript from Webinar: CGT Access Model Overview. February 6, 2024, Online: https://www.cms.gov/files/document/cgt-model-ovw-webinar-2-6-24-transcript.pdf

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Charge compression, price transparency, and NTAP 'lesser of' language combine to create a challenge that is impossible for hospitals to successfully navigate

In the proposed rule, CMS precedes its proposal to increase the NTAP percentage for SCD gene therapies to 75% by stating:

> *Although we still believe it is prudent to proceed cautiously with increasing the new technology add-on payment percentage, we recognize that SCD, the most common inherited blood disorder, has historically had limited treatment options. In addition, hospitalizations and other health episodes related to SCD cost the health system $3 billion per year. We further note that the administration has identified a need to address SCD and has made a commitment to improving outcomes for patients with SCD by facilitating access to cell and gene therapies that treat SCD. Accordingly, we believe that further facilitating access to these gene therapies for Medicare beneficiaries with SCD may have the potential to simultaneously improve the health of impacted Medicare beneficiaries and potentially lead to long-term savings in the Medicare program.* ***We also note that some gene therapies that treat SCD are among the costliest treatments to date, and we are concerned about a hospital's ability to sustain a potential financial loss to provide access to such treatments****.…With this incremental increase, we believe hospitals would continue to have* ***an incentive to balance the desirability of using the new technology for patients as medically appropriate while also maintaining an incentive for continued cost-effective behavior in relation to the overall costs of the case.***[11]

ASTCT appreciates and agrees with CMS' well-founded concern about hospital financial sustainability. Given the limited MS-DRG base payment and a proposed fixed-loss outlier threshold of more than $49,000, hospitals will already contribute more than their fair share of lost dollars when they provide intensive clinical care to SCD patients for the expected 3-6 week administration hospitalization, even if the product was paid for at 100% of cost.[12,13]

In order to avail themselves of any amount of either NTAP or outlier dollars, hospitals will have to mark-up these HSC gene therapy products in accordance with their CCRs. Requiring hospitals to mark-up multimillion dollar products is highly problematic in an era of price transparency. Moreover, it is ineffective at achieving *adequate* reimbursement due to CMS' 'lesser of' NTAP payment formula, a high fixed-loss outlier threshold, and the different CCRs used in payment formulas vs. future rate-setting.

In prior letters, ASTCT has called attention to the ongoing issues with charge compression for drugs and biologics, particularly for high-cost drugs. If a hospital follows CMS' guidance and sets its charges for these therapies in accordance with its own CCR, it is entirely justifiable that a hospital with a CCR of 0.25 would list the charges for these therapies at amounts between **$10-12 million dollars**. Those numbers are astronomical and give our membership extreme pause given price transparency requirements and the lack of Medicare payment system knowledge by the press, consumers, and others who write or read about hospital charging practices. Our members have expressed the view that setting charges north of *$10 million per administration* for gene therapies indicated for a historically vulnerable and underserved population is likely to be perceived as ethically problematic at best—and predatory at worst.

[11] Proposed Rule, pp. 455-456.
[12] Lygenia.com. Your Lygenia FAQs answered. Accessed May 2, 2024. Online: www.lyfgenia.com
[13] Casgevy.com. A guide to your treatment journey. Accessed May 2, 2024. Online: www.casgevy.com

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In addition to charging practice concerns, CMS' precdent of utilizing a case-weighted average of two substantially similar product costs to calculate the dollar amount that would be eligible for NTAP payment will be problematic.[14] If CMS applies this same methodology—and if we assume that the distribution between cases is roughly 50% due to equivalence in FDA label indications—the calculations would produce a case-weighted product cost of $2.65 million.[15] However, hospitals' product acquisition cost will not be $2.65 million; instead, they will incur a specific product cost of either $2.2 million or $3.1 million based on which one they purchase. This is a difference of ***$800,000***, not a few hundred or few thousand dollars, as has been the case with past products. In either case, an individual product cost billed against the 75% threshold for a case-weighted average product cost will still result in massive losses for providers due to the 'lesser of' portion of the NTAP formula.

Modeling Impact to Hospitals

To understand the function and general impact of CMS' proposal to increase the NTAP cap to 75% for these SCD gene therapies, ASTCT prepared a simplified model of reimbursement for two hospitals, Hospital A and Hospital B. As we detail below, this model demonstrates that even the hospitals that charge appropriately for these therapies and receive the maximum 75% NTAP amount will face a significant financial loss.

ASTCT's model assumes that, other than different mark-up practices on the gene therapy products, all paramters are identical between the two facilities. Specifically, both Hospitals A and B:

- Are certified by both manufacturers to provide their HSC gene therapies for SCD;
- Pay the manufacturer $2.65M to acquire the product (an average of the two product prices);
- Have a wage index of 1.0 and no other hospital-specific adjustments to their MS-DRG payment;
- Have an overall CCR of 0.25;
- Have a 30-day inpatient stay during which the HSC gene therapy is administered and which results in identical patient care charges.[16]

The only difference between Hospital A and B is how they apply a mark-up to the $2.65M gene therapy product cost:

- Hospital A applied a 1.1x mark-up (i.e., its standard 10% policy)
- Hospital B applied a 4.0x mark-up (consistent with its CCR of 0.25).

The result, as shown in the green bars below, is that the hospitals have very different product charges and, hence, very different total claim charges—*despite the fact that patient care charges are identical*. This leads CMS to compute a very different case cost estimate for each hospital when the agency multiplies total covered claim charges by the hospital's own overall operating and capital CCRs.

As shown in the light yellow bar below, CMS' calculated cost for Hospital A has no functional relationship to the actual cost incurred by the hospital.

[14] CMS. FY 2023 IPPS Final Rule, FR Vol. 87, No. 153, p. 48925. August 10, 2022. Online: https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-16472.pdf

[15] Calculations based on CMS methodology in FY 2023 CARVYKTI NTAP decision (see prior reference).
Exa-cel: .5*$2.2M = $1.1M; Lovo-cel: .5*$3.1M = $1.55M. $1.55M+$1.1M=$2.65M

[16] To calculate the patient care cost, we assumed a 30-day inpatient stay based on estimates from both companies' patient journey materials. We determined a daily charge amount of $11,890.77 based on dividing the arithmetic mean charge associated with MS-DRG 016 in the FY 2025 IPPS proposed AOR/BOR file (from the AOR v42 grouper tab) by the average length of stay. We then multiplied that amount by 30 days to arrive at patient care charges of $356,723.

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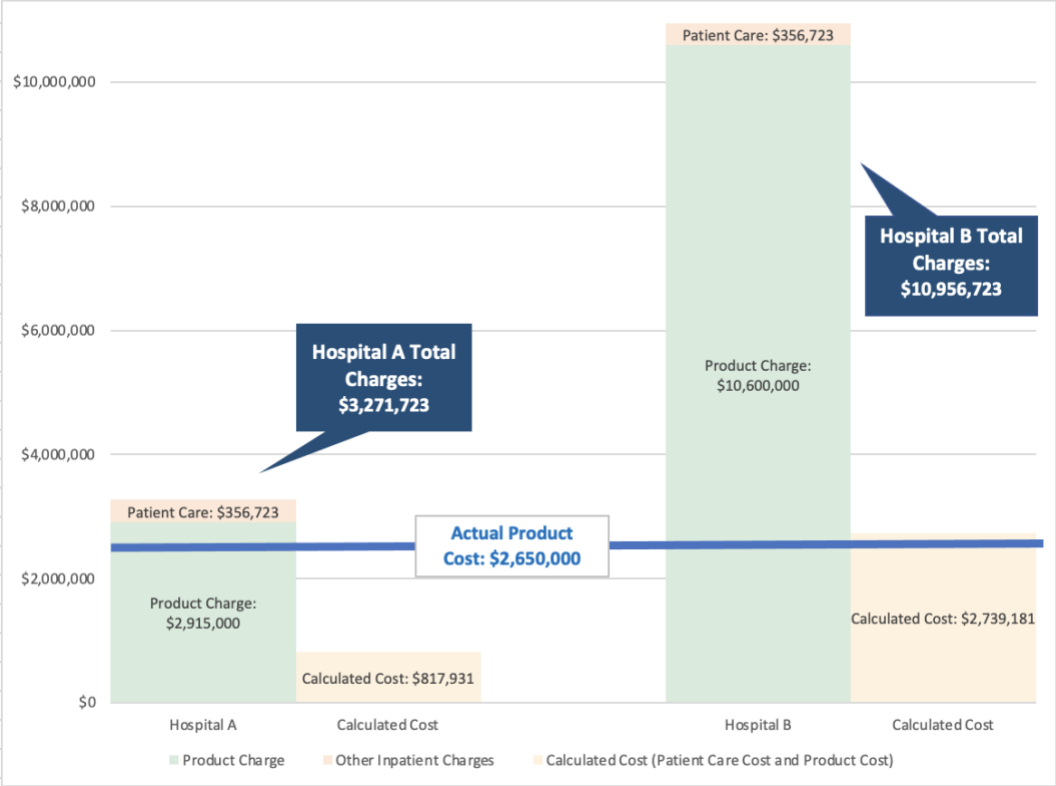

CMS then uses its computed case cost to determine NTAP and outlier payments. This results in very different overall payments to the hospitals, as shown in the chart on the following page.

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- Hospital A:
  - Does not reach the 75% NTAP cap that is being proposed for these products
  - Does not have residual costs and thus does not trigger any outlier payment
  - Has a total payment of $739,798

- Hospital B:
  - Reaches the 75% NTAP cap that is being proposed for these products
  - Has residual cost which triggers an outlier payment
  - Has a total payment of $2,558,069

These examples show that even a hospital that charges in accordance with its cost-to-charge ratio and can access the full proposed 75% NTAP cap receives payment that is still less than the cost to acquire the HSC gene therapy product.

The total payment provides no additional dollars to pay for the inpatient stay required to deliver the therapy to the patient, creating a total loss for the hospital on clinical care provision.

Under this simplified example, we assume that the calculated cost for the patient care charges is the true cost that the hospital incurred for those services and the product cost of $2.65M. As a result, Hospital A would face a loss of **-$1,999,383**, while Hospital B would face a loss of **-$181,112**. These losses are massive: even Hospital B's lower losses are more than three times the proposed fixed-loss outlier threshold. These losses have the same magnitude when modeling the use of actual individual product prices, as well.

This simple example demonstrates that even the "best case scenario" for hospital reimbursement reflecting CMS' proposed NTAP cap increase for FY 2025 will be insufficient—even for hospitals that charge appropriately and avail themselves of the full increased NTAP amount.

The 'lesser of' language inherent to the current NTAP formula means that even when hospitals set their charges appropriately, they will be well short of even the product acquisition cost—a multimillion dollar biologic for which a hospital has to pay for directly. In combination with a complex and lengthy hospital stay, this part of the formula means that hospitals are faced with financial choices that range from terrible to prohibitive. In a theoretical situation where hospitals still move forward with treatment despite the huge negative financial impact expected if CMS implements a 75% NTAP, these SCD cases will be paid in large part through outlier dollars, as shown in our Hospital A and B examples. They will, as a result, add to the confluence of factors pushing the rapid increase in the fixed-loss outlier threshold.

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Limited NTAP budget impact

ASTCT's proposal makes the provision of these therapies feasible for hospitals but will have very limited total fiscal impact to CMS because of a limited number of treatments that will happen in the next few years. First, there is a relatively small number of hospitals approved by manufacturers to administer these gene therapies. Second, the patient journey is complex and lengthy; centers will only proceed with a few cases at a time. Related to that issue, the processes of collecting cells, manufacturing individual products, and administering them take the better part of a calendar year—the patient journey descriptions for these products depict a minimum time frame of 7-8 months per person.[17,18] Last, manufacturers' capacity is finite; as an example, bluebird bio estimated between 85-105 patient "starts" for lovo-cel in all of 2024.[19]

Given that Medicare beneficiaries are likely to be a small percentage of the broader patient payer mix, use of NTAP funds in the manner requested by ASTCT will be inherently self-limiting in terms of the overall impact to Medicare spending. Additionally, as the American Hospital Association noted in a prior letter to CMS, the agency has not typically fully spent the pool of NTAP dollars it allocates.[20]

Developing data for future payment mechanisms

ASTCT fundamentally believes that CMS must move away from typical rate-setting practices for therapies in which product costs overwhelm patient care costs. At the end of the NTAP timeframe, CMS will need to create a new MS-DRG and/or an alternate payment mechanism to reflect the resources utilized to administer these therapies. If it does not, the agency will risk substantially overpaying for a typical autologous SCT within MS-DRGs 016 and 017 while creating a severe underpayment situation for cases using an HSC gene therapy.

Adopting ASTCT's alternate NTAP proposal will create access to these therapies while also providing CMS with the claims data it prefers to use when developing future payment models. These claims will include information on:

- Case volume and clinical care costs: While the HSC gene therapy cases will likely be cumulatively low-volume for the foreseeable future, ASTCT's proposal will support the accrual of case volume for Medicare beneficiaries over the NTAP time period. For CMS to propose or implement any post-NTAP novel payment methodology, it will need at least some cases in order to study the clinical care patterns and resource use.

- Transparent product acquisition cost: Like CAR-T and the other FDA-approved cellular therapies, HSC gene therapy cases are unusual across the MS-DRG system since the product acquisition costs are many multiples of clinical care costs. Using the value code will allow CMS to track the price at which hospitals purchase the gene therapies. It can then learn how best to account for realistic patterns in how hospitals are able to procure these products as the agency builds a durable post-NTAP payment mechanism.

[17] Casgevy.com. A Guide to Your Patient Journey. Accessed May 15, 2024. Online: https://www.casgevy.com/sickle-cell-disease/sites/default/files/treatment-journey-brochure-SCD_Desktop.pdf
[18] Lyfgenia.com. Steps to Treatment. Accessed May 15, 2024. Online: https://www.lyfgenia.com/sickle-cell-treatment-journey
[19] Bluebird Bio. bluebird bio Provides Update on Commercial Launch Progress, Program Milestones, and 2024 Financial Outlook. January 8, 2024. Online: https://investor.bluebirdbio.com/news-releases/news-release-details/bluebird-bio-provides-update-commercial-launch-progress-0
[20] American Hospital Association. AHA FY 2020 IPPS Proposed Rule Comment Letter; Analysis of data from FY 2013-FY 2018. June 24, 2019. Online: https://www.aha.org/system/files/media/file/2019/06/aha-comments-cms-inpatient-pps-fy-2020-proposed-rule-6-24-2019.pdf

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CMS has not provided feedback on stakeholders' alternative suggestions made during past rule-making cycles

Since 2017, ASTCT has indicated our concerns over how high-cost innovative therapies delivered to hospital inpatients will be reimbursed through the current payment system structures. In the past several rule-making cycles, CMS has appeared to be receptive to changing how the IPPS works, given that the agency has repeatedly released Requests for Information (RFIs) soliciting stakeholders' input on how to address innovative therapies and rare diseases. CMS has also requested feedback on the traditional divisions between operating and non-operating room cases within the MS-DRG structure, noting that it will evaluate stakeholder suggestions for future rule-making.

In the spirit of collaborative partnership, ASTCT has spent significant time and resources proactively developing and evaluating potential solutions that are based on CMS' own payment logic and decision-making precedents. In addition to comments provided during the public response periods for each rule, ASTCT has also submitted extensive proposals during the DRG modification comment period that occurs each Fall. In these communications, ASTCT and other organizations have repeatedly flagged the same fundamental issues for CMS: high product acquisition costs, the 'lesser of' portion of the NTAP formula, hospitals being forced to apply mark-ups in order to reverse-engineer CMS' cost calculation formulas, the impact of charge compression on future rate-setting, and the general need for novel solutions in response to the approval of novel therapies.

Over just the past five IPPS rulemaking cycles, ASTCT has made the following suggestions and requests to CMS:

- Convene Town Hall sessions and conduct meetings with stakeholders that are engaged with CGT products to discuss potential payment mechanism innovation;
- Evaluate the creation of separate MS-DRGs for CGT episodes of care: one for the clinical care and one for product acquisition costs;
- Create a new MS-DRG for autologous HSC gene therapies for the FY 2025 cycle;
- Propose a new payment mechanism for acquisition of the HSC gene therapy products;
- Explore methods to include Medicare beneficiaries and dual-eligible beneficiaries in the CMMI CGT Access Model; and
- Utilize a temporary CCR (the "other" CCR) as CMS works toward more accurate development of MS-DRG base payment rates.

Given the influx of input and suggestions provided to CMS, ASTCT expected the agency would have included a rationale in this Proposed Rule as to why it chose to propose a modest increase to the NTAP cap instead of something else. We are genuinely perplexed by the agency's lack of engagement with the stakeholder community on these issues as it is in direct contradiction to the multiple RFIs CMS has issued and the statements it has made about considering feedback in future rule-making. The existing IPPS structure has served its purpose for decades, but it needs modernization to meet the scientific moment and provide beneficiaries with the long-awaited innovative therapies that are now available.

ASTCT is ready and willing to continue to engage with CMS on how to thoughtfully improve beneficiaries' access to these therapies, but our Society needs feedback from CMS in order to move forward. We urge CMS to adopt our recommendations and provide additional feedback in the IPPS Final Rule.

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NTAP for gene therapies should not be contingent on purchasing arrangements

In the Proposed Rule, CMS asks for feedback on whether the 75% NTAP amount should be applicable to only certain applicants who meet additional criteria, specifically:

> *…such as attesting to offering and/or participating in outcome-based pricing arrangements with purchasers (without regard to whether the specific purchaser availed itself of the outcome-based arrangements), or otherwise engaging in behaviors that promote access to these therapies at lower cost.* [21]

IPPS hospitals are currently operating within a "buy-and-bill" environment without access to alternative contracting mechanisms, outcomes-based pricing arrangements, or other opportunities to control these therapies' prices. Unless CMS links the CMMI efforts to negotiate prices to Medicare FFS beneficiaries, these additional considerations will not apply to our member providers and their hospitals.

ASTCT requests that CMS not make NTAP payment for these therapies contingent on manufacturer participation in pricing arrangements, as they are irrelevant to the Medicare beneficiary population.

CMS Response: ***Comment:*** *Commenters opposed limiting the increase in the new technology add-on payment percentage to applicants that met certain additional criteria, such as attesting to offering and/or participating in outcomes-based pricing arrangements. A few of the commenters stated that CMS should not require additional criteria beyond the existing criteria of newness, cost, and substantial clinical improvement. Other commenters stated that CMS did not provide sufficient information regarding the feedback it is requesting related to outcomes-based arrangements, details on how it would operationalize such a requirement, or discuss the potential impact on claims data. They further stated that CMS must describe what arrangements or behaviors it is considering, in addition to the rationale and legal basis for any related proposal, so that stakeholders can appropriately comment on a proposal that has sufficient detail for effective evaluation via notice and comment rulemaking. A commenter stated that CMS should also consider the variability in such arrangements, which could lead to substantial inequities in which therapy patients would be able to access if this was a requirement to receive the new technology add-on payment amount, as well as the competitive disadvantage that may occur. A commenter stated that any such restrictions as described in CMS's proposal would impact patient access to transformative therapies by placing undue burden on providers and payers. The commenter further stated that a variety of factors may inhibit a manufacturer's ability to offer or participate in such arrangements, including lack of clarity in best price reporting, limited resources available within states to establish such agreements, and time needed to measure outcomes for new products. A commenter explained that IPPS hospitals are operating within a "buy-and-bill" environment without access to alternative contracting mechanisms, outcomes-based pricing arrangements, or other opportunities to control these therapies' prices, and that unless CMS links the Center for Medicare & Medicaid Innovation's (CMS Innovation Center) CGT Access Model efforts to Medicare FFS beneficiaries, these considerations would not apply to its member providers and hospitals. Another commenter stated that the arrangements CMS describes are encouraged to take place under the CMS Innovation Center's CGT Access Model and new technology add-on payment should not be tied to participation in the model, which is still under development. A commenter also stated that mandates related to outcomes-based pricing arrangements are not provided in the new technology add-on payment statute, and there is currently no mechanism by which FFS Medicare can*

[21] Proposed Rule, p. 456.

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engage in value-based payment arrangements. A commenter stated that CMS should work closely with impacted stakeholders before considering developing an alternative pricing requirement in the future to ensure any proposal would align with the new technology add-on payment program goals. Some commenters further stated that it is not clear how such additional criteria relate to or advance the purpose of the new technology add-on payment program.

Response: *We appreciate the feedback from commenters. We note that we were seeking comments regarding other criteria that could demonstrate that applicants were engaging in behaviors that promote access to these therapies at lower cost, in alignment with the Administration's broader effort to further drive down prescription drug costs. Consistent with our concerns about incentives for manufacturers to increase prices, we continue to welcome comments on this topic for future consideration. At this time, we are not making this 75 percent add-on payment percentage available only to applicants that meet certain additional criteria, but we will continue to evaluate this topic and may consider changes in the future. (pp. 660-662)*

ASTCT Concerns RE: Access to Gene Therapies: ***Comment:*** *A few commenters disagreed with CMS's proposal, stating that a new technology add-on payment of 75 percent will not create access to gene therapies. The commenters stated that a new technology add-on payment rate of 75 percent for these costly therapies would still leave a significant burden of unreimbursed costs on hospitals, while keeping drug manufacturers financially whole. The commenters stated that this would represent an unsustainable model for reimbursement and may disincentivize hospitals from providing these therapies, potentially leading to access issues for patients.*

A commenter stated that CMS did not discuss its evaluation of any other solutions for improving the overall MS-DRG payment system, nor propose any other solutions for gene therapies, despite stakeholders having provided many ideas in the past. The commenter stated that CMS risked creating a two-tier system by fostering innovation for Medicaid patients via the CMS Innovation Center's new CGT Access Model, while offering no solutions for traditional Medicare FFS or Medicaid-Medicare dual-eligible patients with SCD or TDT, and did not view the proposal to be in harmony with the attention and effort being put into the CMS Innovation Center model. The commenter also asserted that the new technology add-on payment increase that CMS proposed does not address the series of compounding losses for hospitals that wish to provide these therapies: a low base MS-DRG payment rate, an inadequate new technology addon payment percentage, the highest-ever fixed-loss threshold, and recovery of only 80 percent of remaining calculated costs through the outlier formula, which it stated directly obstruct Medicare patients' access to gene therapies. The commenter requested that CMS reimburse hospitals for 100 percent of their product acquisition costs related to gene therapies for SCD and TDT, potentially using CMS's adjustment authority under section 1886(d)(5)(I) of the Act. The commenter stated that this request could be operationalized by requiring hospitals to use value code 90 to report the product acquisition cost, providing payment at 100 percent of the reported product cost, and remove the charges reported in revenue code 0892 when calculating total case payment in determining whether an outlier payment is warranted. The commenter explained that hospitals would still be incentivized to provide cost-effective care, as the MS-DRG payment and outlier calculations would still be applicable to the clinical care portion of the claim. The commenter also expressed concern that charge compression, price transparency, and new technology add-on payment 'lesser of' language combined to create a challenge that is impossible for hospitals to successfully navigate, as it stated that this required hospitals to markup multimillion dollar products, and was ineffective at achieving adequate reimbursement. The commenter asserted that if a hospital set charges for these therapies in accordance with its own CCR, it was entirely justifiable that a hospital would list the charges between $10 to 12 million, but was likely to be perceived as ethically problematic and predatory. In further support of its

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assertions, the commenter modeled the impact to hospitals using a simplified model of reimbursement for two hospitals, with one using a 10 percent policy and one using a CCR of 0.25 to mark-up the gene therapy product costs, to demonstrate that even hospitals that charged appropriately for these therapies and received the maximum 75 percent new technology add-on payment amount would face a significant financial loss. The commenter stated that the results showed that the hospitals had very different product charges, with different total claim charges— despite the fact that patient care charges are identical, leading CMS to compute a very different case cost estimate for each hospital. The commenter stated that the 'lesser of' language used for new technology add-on payment meant that even when hospitals set their charges appropriately, they would be underpaid even the product acquisition cost, resulting in prohibitive financial choices, and where costs would largely be paid through outlier dollars. The commenter asserted that its proposal would have a limited total fiscal impact to CMS because of the limited number of treatments that will happen in the next few years, and the small percentage of applicable Medicare beneficiaries. The commenter referenced a prior letter from the American Hospital Association to CMS, asserting that CMS has not typically fully spent the pool of new technology add-on payment dollars it allocates. The commenter further stated that adopting its proposal would allow for claims data with information on case volume, clinical care costs, and transparent product acquisition costs that could be used at the new technology add-on payment timeframe to create a new MS-DRG and/or an alternate payment mechanism to reflect the resources utilized to administer these therapies. Finally, the commenter noted a variety of suggestions it had previously provided, including Town Hall sessions, evaluating the creation of separate MS-DRGs for clinical care and product acquisition costs, creating a new MS-DRG, proposing new payment mechanism for acquisition of HSC gene therapy products, adding Medicare and dual-eligible beneficiaries in the CMS Innovation Center's CGT Access Model, and using a temporary CCR, and stated it was not clear as to why the agency chose to propose an increase to the new technology add-on payment percentage instead.

Some commenters stated that, while they were supportive of the proposed increase in payment for SCD gene therapies, they were concerned that the change would not adequately address gaps in payment or access issues for these therapies. A commenter stated that the SCD gene therapies map to DRGs that have base rates far below the costs of these products, and that reimbursement only covers a minimal portion of the drug cost and no provider and facility costs for the 30-days of inpatient care. (pp. 662-665)

Multiple commenters also discussed similar concerns generally with new technology addon payment methodology and in particular for costly therapies. They referenced the practice of "charge compression" due to CCRs and the way that the add-on payment amount is calculated as the "lesser of" two different values, which they stated results in hospitals incurring at least 35 percent of the new technology costs even with the new technology add-on payment (based on a 65 percent maximum add-on payment). Another commenter also suggested that CMS should eliminate the "lesser of" new technology add-on payment methodology for gene therapies targeting SCD and other technologies, which it stated required hospitals to artificially inflate their charges to obtain appropriate reimbursement. (p. 665)

Response: *We appreciate the commenters' feedback. We note that the prospective payment system is an average-based system and it is expected that some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. In deciding which treatment is most appropriate for any particular patient, physicians are expected to balance the clinical needs of patients with the efficacy and costliness of particular treatments. We continue to believe that changing the "lesser of" methodology, using the acquisition costs, or otherwise further increasing the add-on payment percentage would remove consideration of the costs of new technology from treatment decisions, and that it is important to maintain some incentive to weigh the costs of new technology in making clinical decisions. Similar to our discussion in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42299), we believe*

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that paying hospitals for 100 percent of their product acquisition costs related to gene therapies would result in very little of the incentives inherent to the prospective payment system.

We also disagree with the commenter that this proposal, or other suggestions offered by other commenters, would have a limited total fiscal impact to CMS because of the limited number of treatments that will happen in the next few years and the small percentage of applicable Medicare beneficiaries. With regard to the commenter's statement regarding a pool of new technology add-on payment dollars that are allocated, we note that CMS does not allocate dollars to new technology add-on payments. We note that the citation provided by the commenter indicated that when implementing the new technology add-on payment in the September 7, 2001 final rule (66 FR 46902), CMS set a target limit for these payments at 1 percent of total operating prospective payments. However, the new mechanism was initially required to be implemented in a budget neutral manner, and as we had noted at that time, this limit was set to address CMS's concern that new technology add-on payments should not result in inappropriately large redistributions of payments from hospitals that do not employ new technology to those that do (66 FR 46920). In the FY 2005 IPPS final rule, we provided an update, that as a result of the enactment of section 503(d) of Public Law 108-173, we will no longer include the impact of additional payments for new medical services and technologies in the budget neutrality factor (69 FR 49084). Due to the high cost of these gene therapy technologies, and because the total number of patients that will receive these treatments and the amount of new technology add-on payments associated with care of these patients in the future is unknown, it is unclear to us that the fiscal impact to CMS would be limited. We also note that because new technology add-on payments are not administered in a budget neutral manner, by default, they have the potential to result in increases to Medicare spending that are unpredictable and beyond our control, which is why we have remained cautious when assessing potential changes to the new technology add-on payment program to maintain the incentives inherent to the prospective payment system. (p. 665)

Comment: *Many commenters stated that the Agency should work with stakeholders to identify adequate and sustainable reimbursement mechanisms for covering payment of outlier drug acquisition costs for both SCD and for other life-saving cell and gene therapies. Commenters stated that the current payment system was not designed to address market developments including rapid introduction of therapies with high costs, and was not sufficient to appropriately reimburse hospitals. Some commenters were particularly concerned about Medicare payment for these therapies after the new technology add-on payment expires, stating that the current MS-DRGs assigned have reimbursement rates inadequate to reimburse these high-cost therapies. The commenters urged CMS to consider alternative methods of reimbursement to support appropriate patient access in accordance with the goals of this proposal such as a continued pass-through payment for the gene therapies or some other mechanism, stating that the MS-DRG system was not structured to support therapies as costly as these SCD gene therapies. A commenter further stated the need for CMS to develop longer-term solutions to ensure reimbursement sustainability, and that a CMS-convened Town Hall session may be beneficial to facilitate innovative solutions. Commenters also suggested other potential pathways such as the creation of new MS-DRGs for high-cost treatments, and changes to the role of costto-charge ratios (CCRs) in the reimbursement methodology, such as eliminating the role of CCRs or creating a new CCR for more accurate rate-setting. A commenter further stated that these options are already within CMS's statutory authority and implementable through notice and comment rulemaking. The commenter further believed Congress must permanently resolve how to pay for these therapies, preferably through broad-scale reform of national drug development, production, and distribution policies. The commenter recommended that in the meantime, CMS work with Congress on changes specific to coverage and payment, such as by carving payment for these products out of the DRG system, as currently done for solid organ and stem cell*

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transplants, or other policies, including split-DRGs, that would enable hospitals to recoup all their costs for these therapies.

A commenter voiced concerns over the rise of high-cost therapies generally and CMS's ability to appropriately account for their costs when determining payments to hospitals and health systems, urging CMS to examine the adequacy of its payments to hospitals. The commenter noted that many of these therapies' prices are beyond what would have been predicted when the inpatient PPS system was designed, and they are therefore adding to the existing and rising challenge of paying for a massive increase in high-cost therapies and technologies in health care.

Response: *We thank commenters for their feedback and suggestions. As noted by commenters, longer-term solutions are outside of the scope of the new technology add-on payment program and this rulemaking. We will continue to consider these issues. Therefore, after consideration of the public comments received, for the reasons discussed previously and in the FY 2025 IPPS/LTCH PPS proposed rule, we are finalizing our policy as proposed. We are finalizing that for certain gene therapies approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule that are indicated and used specifically for the treatment of SCD, effective with discharges on or after October 1, 2024 and concluding at the end of the 2- to 3-year newness period for such therapy, if the costs of a discharge (determined by applying CCRs as described in § 412.84(h)) involving the use of such therapy for the treatment of SCD exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. We note that these payment amounts would only apply to Casgevy™ (exagamglogene autotemcel) and Lyfgenia™ (lovotibeglogene autotemcel), when indicated and used specifically for the treatment of SCD, which CMS has determined in this FY 2025 IPPS/LTCH PPS final rule meet the criteria for approval for new technology add-on payment. We are also adding new § 412.88(a)(2)(ii)(C) and (b)(2)(iv) to reflect this change to the calculation of the new technology add-on payment amount, beginning in FY 2025 and concluding at the end of the 2- to 3-year newness period for each such therapy. As noted earlier, we will continue to assess this policy and may propose changes in the future.* (pp. 666-668)

Hospitals need confirmation of coverage for gene therapy

Separate from payment policy proposals, CMS has yet to clarify national coverage of the HSC gene therapies for Medicare beneficiaries or require MACs to issue local documentation in a timely manner.

The following is listed in the CMMI Model's "Frequently Asked Questions" document:

> *9. This model starts in 2024, do Medicare and Medicare cover this therapy now?*
>
> *Improving access to these therapies – both before and after the launch of the model – is a key goal of CMS. Prior to the launch of the model, current Medicare and Medicaid access standards will apply,* ***which will result in access as currently required by law****.*[22]

Hospitals are aware that these HSC gene therapies are FDA-approved biologics that meet statutory requirements—i.e., they are part of a covered benefit category and performed as part of autologous SCT,

[22] CMS.gov. CGT Access Model Frequently Asked Questions. Accessed May 22, 2024. Online: https://www.cms.gov/cgt-access-model-frequently-asked-questions

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an inpatient hospital service that is reasonable and necessary for the treatment of an illness.[23] However, the National Coverage Determination for Stem Cell Transplantation (110.23) does not include SCD or TDT within the explicitly covered or non-covered indication list for autologous SCT. As a result, coverage is up to the MACs' discretion on a claim-by-claim determination process.

The acquisition costs of these products are far beyond those of any other item or service provided to a beneficiary during the normal course of care. Without confirmation of coverage in advance of proceeding, or the ability to seek a binding prior authorization for a specific patient, hospitals face a post-care claim determination process. This creates a financial risk that the most hospitals will be unable to take without confirmation of coverage in advance, which will further limit patient access.

CMS recently gave notice of a coordinated Local Coverage Determination (LCD) proposal for Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL36377). The agency cited the need to *"make sure that Medicare covers, and people with Medicare have access to, skin substitute products that are supported by evidence…and that coverage aligns with professional guidelines for appropriately managing these wounds."*[24] We support the use of a similar coordinated model for the HSC gene therapies.

ASTCT requests that CMS require MACs to confirm that these HSC gene therapies will be covered per the FDA labels for SCD and TDT before the start of FY 2025.

CMS Response: CMS did not respond to this request.

Proposal to implement April 1 as new 3-Year Anniversary Date in FY 2026

CMS proposes, beginning in FY 2026, to amend the current practice of using April 1 as the date for determining whether a newness anniversary date would qualify a technology for a potential third year of NTAP. This is an important adjustment, given that CMS changed its FDA approval deadline from July 1 to May 1 in FY 2024. CMS' proposal will be particularly helpful in accruing data for low-volume technologies and/or those with a significant delay between their newness date and the timeframe when claims began accumulating in the data.

ASTCT supports CMS' proposal to amend the current practice of using April 1 as date for assessing whether a newness anniversary date qualifies a technology for a potential third year of NTAP.

CMS Responses:

- **April 1 Anniversary Date**: *We thank commenters for their support of our proposal, and agree that this proposal would provide additional flexibility for new technology add-on payment applications submitted in accordance with the change in the FDA marketing authorization deadline.* (p. 628) *Therefore, after consideration of the comments received, and for the reasons discussed previously and in the FY 2025 IPPS/LTCH PPS proposed rule, we are finalizing our proposal that, beginning*

[23] CMS.gov. Medicare Coverage of Items and Services. Accessed May 8, 2024. Online: https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/coverage/medicare-coverage-items-and-services

[24] CMS.gov Newsroom. CMS Statement on Proposed Local Coverage Determination (LCD) for Skin Substitute Grants/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers. Accessed May 22, 2024. Online: https://www.cms.gov/newsroom/press-releases/cms-statement-proposed-local-coverage-determination-lcd-skin-substitute-grafts/cellular-and-tissue

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with new technology add-on payments for FY 2026, in assessing whether to continue the new technology add-on payments for those technologies that are first approved for new technology add-on payments in FY 2025 or a subsequent year, we will extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1 of that fiscal year. This policy change will become effective beginning with those technologies that are initially approved for new technology add-on payments in FY 2025 or a subsequent year. For technologies that were first approved for new technology add-on payments prior to FY 2025, including for technologies we determine to be substantially similar to those technologies, we will continue to use the midpoint of the upcoming fiscal year (April 1) when determining whether a technology would still be considered "new" for purposes of new technology add-on payments. Similarly, we are also finalizing that beginning with applications for new technology add-on payments for FY 2026, we will use the start of the fiscal year (October 1) instead of April 1 to determine whether to approve new technology add-on payment for that fiscal year. (pp.634-635)

- **Extending Third Year to All New Technologies:** *We thank commenters for their feedback. However, we do not agree that we should guarantee a third year of new technology add-on payment for all technologies regardless of when they receive FDA marketing authorization. The intent of our policy was not to ensure that more technologies would receive three years of new technology add-on payments, but rather to address how the change in the FDA marketing authorization deadline, effective beginning with new technology add-on payment applications for FY 2025, may limit the ability of new technology add-on payment applicants to be eligible for a third year of new technology add-on payments under our general practice for determining whether to extend the payment for an additional fiscal year, as described previously in this rule. We recognize that there may be a small subset of technologies that would not benefit from this proposal.*

  As we stated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58955), section 1886(d)(5)(K)(ii) of the Act establishes a period of not less than 2 years and not more than 3 years for the collection of data with respect to the costs of new services or technologies; a full 3 years is not required. As we had stated, consistent with the statute and our implementing regulations, a technology is no longer considered "new" once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349). As such, once a technology has been available on the U.S. market for more than 2 to 3 years, we consider the costs to be included in the MS-DRG relative weights regardless of whether the technology's use in the Medicare population has been frequent or infrequent. Therefore, we do not believe that 2 years' worth of data would be insufficient to inform rate-setting for the inpatient setting.

  We also disagree that this proposed policy would leave CMS with unreliable claims data for ratesetting for technologies that would be on the market for a year or more before they could begin receiving new technology add-on payment and receive payment for at most two years based on their FDA marketing authorization dates. 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. Any eligible outlier payment is added to the DRG-adjusted base payment rate (88 FR 58648). We further note that whether a technology receives new technology add-on payments or not does not affect coverage of the

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technology or the ability for hospitals to provide a technology to patients where appropriate. Therefore, data reflecting the costs of a new technology begin to become available for recalibration of the DRG weights starting from when the technology became available on the U.S. market. As we previously stated, the newness period does not necessarily start with the approval date for the medical service or technology and does not necessarily start with the issuance of a distinct code. Instead, it begins with availability of the product on the market, which is when data become available (69 FR 49003) (pp. 631-632)

- **Newness Period Definition:** *As we have stated in prior rulemaking, the newness period does not necessarily start with the approval date for the medical service or technology and does not necessarily start with the issuance of a distinct code. Instead, it begins with availability of the product on the market, which is when data become available. We have consistently applied this standard, and believe that it is most consistent with the purpose of new technology add-on payments (69 FR 49003).*

  We have also stated that for technologies that do not have a unique ICD-10 code, while it may be impossible to identify when a particular product was used because there is no unique code to identify it amongst other products in the category, the product is nonetheless used and paid for. In addition, hospital charges reflect the services provided to patients receiving the new service or device whether or not a specific code is assigned. Therefore, data containing payments for these new technologies are already in our MedPAR database and when DRG recalibration occurs these costs are accounted for. Furthermore, assignment of new codes can occur for many reasons other than the introduction of new procedures and technologies. For example, new codes can simply reflect more refined and discriminating descriptions of existing procedures and technologies (69 FR 49003). We also disagree that the newness period should start on the date of the first sale or at the first administration of a technology. As we previously noted, while CMS may consider a documented delay in a technology's availability on the U.S. market in determining when the newness period begins, under our historical policy, we do not consider how frequently the medical service or technology has been used in our determination of newness (70 FR 47349). Consistent with the statute, a technology no longer qualifies as new once it is more than 2 to 3 years old irrespective of how frequently it has been used in the Medicare population. (p. 634)
- **Impact of NTAP status on access***: We thank the commenters for their comments and recommendations. We note that, as described previously, patient access to these technologies should not be adversely affected if a technology does not qualify to receive new technology add-on payments, as CMS continues to pay for new technologies through the regular payment mechanism established by the MS–DRG methodology. In addition, and as previously noted, a hospital may be eligible for additional payment for outlier cases. As also previously noted, whether a technology is approved for new technology add-on payments does not affect coverage of the technology or the ability for hospitals to provide a technology to patients where appropriate. We evaluated all applications for FY 2025 that were submitted by the new technology add-on payment deadline under the applicable eligibility requirements, and we will continue to do so for applications that are submitted or resubmitted for FY 2026. We further note that submission of a new technology addon payment application does not guarantee that a technology will be approved for a new technology add-on payment.* (p. 644)
- **Other Comments:** *We received several public comments requesting changes to the new technology add-on payment policies such as creating new alternative pathway categories for different FDA designations or types of treatments, expanding the conditional approval process to additional types of technologies or designations, moving to a biannual process that would set two annual deadlines for*

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manufacturers to apply for new technology add-on payment, and requiring Medicare Advantage (MA) to provide new technology add-on payment. These comments were outside the scope of the proposals included in the FY 2025 IPPS/LTCH PPS proposed rule and we are therefore not addressing them in this final rule. (p.623)

For full discussion of the above items, see pp.623-646

Additional NTAP decisions of ASTCT Member Interest:

- **Casgevy™ for Transfusion-Dependent Beta Thalassemia (TDT):** NTAP Denied (pp. 401-402)
- **Bispecific antibodies for Multiple Myeloma:**
  - ELREXFIO™ and TALVEY™ declared substantial similar to TECVAYLI; all have NTAP status for FY 2025 (pp. 431-433)
- **AMTAGVI™**: NTAP Denied (pp. 505-507)

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

ASTCT continues to appreciate the unique rate-setting methodological changes CMS has implemented for MS-DRG 018 (Chimeric Antigen Receptor T-cell and Other Immunotherapies) in recognition of the fact that a large proportion of the cases assigned to MS-DRG 018 are clinical trial cases. ASTCT continues to invest significant time and resources in educating its members on CMS' coverage, coding, billing, and reimbursement provisions, through conducting webinars and through the release of a *CAR-T Coding & Billing Guide* to highlight and consolidate CMS' instructions for hospitals.[25]

Continuation of Current MS-DRG 018 Payment and Rate-Setting Methodology

ASTCT appreciates that CMS separates cases with product acquisition costs from those without (e.g., clinical trial or expanded access cases) in both the payment and rate-setting methodologies utilized for MS-DRG 018. Given the high product acquisition cost and extensive pipeline of clinical trials associated with the types of immunotherapies included in MS-DRG 018, ASTCT feels the unique methodology CMS has implemented for payment and rate-setting is warranted.

CMS Response: CMS did not respond to this request but no changes to the MS-DRG methodology were made in the Final Rule.

ASTCT requests that CMS maintain its unique methodology for MS-DRG 018 payment and rate-setting for the foreseeable future.

Mitigate Charge Compression for MS-DRG 018 Cases to Pay Cases Appropriately

ASTCT reiterates our concerns and recommendations about charge compression for MS-DRG 018 cases. We have described our position both in comments in the Fixed-Loss Outlier Threshold section earlier in

[25] ASTCT, *CAR-T Coding & Billing Guide*: https://www.astct.org/advocate/car-t-coding-and-billing-guide.

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this letter, and in our comment letter on the FY 2024 IPPS Proposed Rule.[26] Below, we discuss these recommendations again and provide updated numbers for this rule-making cycle. We urge CMS to implement these changes in order to pay hospitals adequately for the care they provide and to simultaneously decrease outlier spending.

ASTCT acknowledges that MS-DRG 018 is the highest-paying DRG in the IPPS system. We also note that the primary driver of the high costs associated with this DRG is the product acquisition cost, which is beyond providers' control—not clinical care costs. 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 they can set charges in accordance with their CCRs,[27] due to the significant charge compression that occurs.

Despite the unique payment and rate-setting practices CMS has implemented for MS-DRG 018, our analysis of the FY 2025 proposed rule data files indicates the following:

- Most MS-DRG 018 cases resulted in outlier payment: 939 cases out of a total of 1,420 (66%);
- $228,185,349 total outlier dollars were spent on these 939 outlier cases.

The 66% of cases that receive outlier dollars is a 5% increase from the 61% of cases that we noted in last year's comment letter. For contextual comparison, this exceeds the next-highest outlier proportion, in MS-DRG (001, Heart Transplant with MCC) by 22%—a clear indication that the rate-setting methodology is not capturing providers' true costs of care.

While the availability of outlier dollars is an important backstop for the IPPS system, it should not be relied upon as a major source of payment for most cases within a single MS-DRG.

By design, a hospital that receives an outlier payment has incurred a financial loss on that case by absorbing the fixed-loss threshold (i.e., more than $49,000 as proposed for FY 2025) and receiving only 80% of the balance beyond that threshold. Losses of this magnitude cannot be made up with thin margins on other cases. CMS' rate-setting methodology (e.g., applying the drug CCR to the pharmacy charges reported on MS-DRG 018 claims) significantly underestimates the CAR-T product cost. This makes sense to ASTCT, as CAR-T is unlike any other drug or biologic captured in the drug CCR.

Since the product acquisition cost far outweighs the clinical care cost, it will be virtually impossible for CMS to create a payment rate based on provider billed charges due to the discrepancy in the CCRs that are applied between payment and rate-setting. This will be the case even if hospitals improve charging practices and set their charges in accordance with their own overall operating and capital ratios, as instructed by CMS. CMS uses completely different CCRs for the purposes of rate-setting than it does when calculating total payment to hospitals for they care they provided.[28] The drug CCR is 0.18, while the average operating and capital CCR of CAR-T hospitals is about 0.25. This mismatch is significant, undervaluing a $450,000 cell therapy product by $31,500 (.07*$450,000) during rate-setting; it will continue to result in an extreme percentage of cases receiving a substantial amount of their total payment from outlier dollars.

[26] ASTCT.org. https://www.astct.org/Advocacy/Policy-Letters-and-Statements
[27] CMS. FY 2022 IPPS Final Rule. Online: https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf (p.192)
[28] CMS. FY 2022 IPPS Final Rule. Online: https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf (p.192)

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Additionally, as cellular therapies expand to more hospitals, the number of low-wage-index hospitals providing CAR-T will increase. These hospitals will receive even lower total reimbursement despite having the same product acquisition costs and these cases will rely heavily on outlier dollars, drawing even further on the pool. This trend will not decrease without intervention; instead, CMS can expect to see it continue to grow significantly unless and until the agency corrects for the charge compression that impacts the base payment of MS-DRG 018.

ASTCT is asking that CMS consider the creation of a threshold test such that when more than X% (e.g. 75%-90%) of the MS-DRG payment comes from a purchased item or service, rather than patient care costs, a unique methodology is used to estimate costs. CMS could use the value code and amount to develop an average cost for use in rate-setting, or it can use a different CCR. Ultimately, the agency must do *something more than it does now* to provide fair payment that is more reflective of the average cost of the case and decreases reliance on outlier dollars.

The March 2023 Medicare Payment Advisory Commission (MedPAC) report acknowledges the problematic nature of payment system inadequacy, stating: "if payments do not cover the marginal costs, the provider may have a disincentive to care for Medicare beneficiaries."[29] ASTCT fears that this disincentive will be pronounced with cell and gene therapies - the small number of hospitals that provide these therapies are currently the only "safety net" for beneficiaries with severe or life-threatening cancers and/or rare illnesses that need highly specialized care. CMS needs to protect these specialized hospitals similar to the way it protects Critical Access Hospitals and other important specialized hospitals.

In response to our detailed comments and recommendation last year, CMS stated the following in the FY 2024 Final Rule:[30]

> *Comment: A commenter requested that CMS utilize the "other" CCR for CAR-T product charges associated with revenue code 0891 to mitigate charge compression problems until CMS data is available for cost center 0078. The commenter stated that this would result in a more appropriate case cost and a higher relative weight for MS-DRG 018.*
>
> *Response: We do not believe it would be appropriate to utilize the "other" CCR for CART product charges associated with revenue code 0891. The categories assigned to the "other" cost center are categorically not described by another cost center. This is not the case for CAR-T product charges, as the drug cost center describes the same type of product. Therefore, we do not believe it is necessary to make changes to the CCR used for CAR T-cell product charges. After consideration of the public comments we received, we are finalizing our proposals without modification.*

ASTCT disagrees with CMS' statement that the "*drug cost center describes the same type of product."* CAR-T and other cellular therapy products assigned to MS-DRG 018 are fundamentally different from other products within the cost center, as has been acknowledged by both the FDA and the National Uniform Billing Committee (NUBC).

When the first CAR-T was approval in August 2017, the FDA issued a press release in which then-FDA Commissioner Scott Gottlieb, MD, stated:

[29] Medicare Payment Advisory Commission (MEDPAC), *Report to Congress: Medicare Payment Policy*, Washington (DC): MedPAC, 2023, page 72: https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/.
[30] CMS. FY 2024 IPPS Final Rule. Online: https://www.govinfo.gov/content/pkg/FR-2023-08-28/pdf/2023-16252.pdf, p. 154

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> *We're entering a new frontier in medical innovation with the ability to reprogram a patient's own cells to attack a deadly cancer… New technologies such as gene and cell therapies hold out the potential to transform medicine and create an inflection point in our ability to treat and even cure many intractable illnesses.*[31]

The FDA has not integrated CAR-T and other cellular therapy products into the routine drug approval processes overseen by the Center for Drug Evaluation and Research (CDER), which handles therapeutic medicines. Rather, cellular therapy products are processed and evaluated through the Center for Biologics Evaluation and Research (CBER), which has a specific charge to regulate cellular and human gene therapy products. In March 2023, the FDA further formalized the differentiation of cellular therapy from traditional drugs with its announcement of a new cell and gene therapy super office and reorganization of staff to *"enhance expertise in cell and gene therapies"* and *"address the substantial growth in the development of innovative, novel products."*[32] The FDA is the ultimate regulator of all therapeutic products utilized by physicians or individuals, and its deliberate separation of cell therapies from other drug products is significant.

The NUBC also recognized the difference between other drug products and cell and gene therapy products. In September 2018, the NUBC created dedicated revenue codes (087x and 089x) for cell and gene therapies, recognizing the fact that these products represent a unique class of drugs/biologics separate from existing pharmacy revenue codes 25x and 63x.[33] NUBC's perspective was reinforced by CMS' creation of a separate line in the cost report (line 0078). This action signaled to ASTCT and its members that CMS viewed cellular therapy products and their associated costs as being different from regular pharmacy costs, and wished to isolate them. With the establishment of cost center 78, cell therapy costs are beginning to be isolated. Additionally, many hospitals accrue the product acquisition costs associated with cellular therapies (such as CAR-T and tumor infiltrating lymphocyte [TIL] products) in the cell lab or SCT department, rather than in pharmacy. Furthermore, CMS has not issued instructions to hospitals to reclassify CAR-T product acquisition costs to the drug cost center.

CAR-T and other cellular therapy product costs continue to be several orders of magnitude higher than any other drugs utilized in the inpatient setting. As of May 2024, Wholesale Acquisition Cost (WAC) ranged between $420,000 - $515,000 for hospitals to acquire a single CAR-T or TIL product. Discounts are not an option for hospitals—bulk purchasing is not possible for person-specific therapies and 340B rates are not accessible for inpatient hospital use.

Low-cost drugs are administered more commonly to inpatients, and hospitals tend to mark-up low-cost drugs at a very high rate; the national drug CCR is, as a result, very low (0.18 for FY 2024). ASTCT acknowledges CMS' explicit guidance in the IPPS Final Rules for FY 2021 and 2022 that providers *should* charge in accordance with their CCRs. While some hospitals have modified their charging practices to account for the current CCRs used in CMS' payment and rate-setting calculations, many health systems are understandably reluctant to mark up product charges commensurate with CMS' payment and rate-setting methodologies. This, in combination with the limited number of hospitals that are certified to provide these specialized therapies and the small volume of patients who receive them, means that the national drug CCR will not be readily impacted by these therapies.

[31] U.S. Food and Drug Administration; FDA approval brings first gene therapy to the United States, August 2017.
[32] U.S. Food and Drug Administration; Establishment of the Office of Therapeutic Products, March 2023.
[33] National Uniform Billing Committee; New Cell/Gene Therapy Codes, September 2018.

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ASTCT repeats our request from last year that CMS utilize the "other" CCR to reduce cellular therapy product charges (i.e., those reported under revenue code 0891) to cost starting in FY 2025 as a strategy to address charge compression. We further recommend that the "other" CCR remain in place until CMS proposes an alternative payment solution.

CMS Response: *We continue to believe it would not be appropriate to utilize the "other" CCR for CAR T-cell therapy product charges associated with revenue code 0891. Under our costbased weight methodology, many revenue codes are mapped to each of the 19 cost centers. We believe that relative to those 19 cost centers, cellular therapies are most similar to drugs given that hospitals have generally calibrated their CAR T-cell therapy product charges to the "drugs" cost center CCR. To provide additional clarity, we have renamed the "drugs" cost center to the "drugs and cellular therapies" cost center. We may consider changes to the CCRs used for gene and cellular therapies in future rulemaking.*

The FY 2025 CCR for Drugs and Cellular Therapies 0.178
(pp. 331- CCR table, 333 – Response text)

Mapping Request

A stakeholder requested that CMS modify the current title of MS-DRG 018. ASTCT notes that the therapy associated with this request, prademagene zamikeracel (PZ-cel), seems to differ significantly (in terms of clinical focus and resources) from the other therapies currently mapped to MS-DRG 018—particularly in that it requires an operating room and subsequent post-surgical care. While CMS does not specifically propose to map PZ-cel to MS-DRG 018 for FY 2025, ASTCT does not think it is a match for the technologies and clinical care currently included in this MS-DRG, given that it is not an immunotherapy and would be the only surgical episode of care in the DRG.

ASTCT requests that CMS not finalize the mapping of PZ-cel to MS-DRG 018 due to differences in resource use.

CMS Response: *We appreciate the commenters' feedback. In response to the commenters who requested that CMS not finalize the mapping for application of PZ to Pre-MDC MS-DRG 018 due to the belief that there are differences in resource use when compared to other therapies currently mapped to Pre-MDC MS-DRG 018, we note that the commenters did not indicate whether they believed the differences in resource use for application of PZ are higher or lower in comparison to the other therapies currently mapped to Pre-MDC MS-DRG 018, nor did the commenters offer any alternative MS-DRG suggestions for CMS's consideration. We acknowledge that application of PZ requires use of an operating room and the administration of other therapies currently assigned to Pre-MDC MS-DRG 018 do not. We also note that consistent with our established process for assigning new diagnosis or new procedure codes to MDCs, MS-DRGs, and the associated attributes (severity level and O.R. status), we examined the MDCs, MS-DRG assignment and O.R. status of the predecessor procedure codes to inform our assignments and designations. As discussed in prior rulemaking and previously in the preamble of this final rule, we review the predecessor code and MS-DRG assignment most closely associated with the new diagnosis or 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 previously noted that this process does not automatically result in the new diagnosis or procedure code being assigned to the same MS-DRG or to have the same designation as the predecessor code. In our evaluation of MS-DRG classification requests under the IPPS MS-DRGs, consideration is also given to*

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the similarities and differences in resource 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 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, while the existing therapies (that is, CAR T-cell and non-CAR T-cell) currently mapped to Pre-MDC MS-DRG 018 may be indicated in the treatment of patients with cancer, 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 that do not have a diagnosis of cancer. In our review of the MS-DRG assignment for application of PZ, we recognized that this technology is defined as an investigational genetically engineered autologous cell 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. 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. For additional information on the CGT Access Model, we refer the reader to the CMS website at https://www.cms.gov/priorities/innovation/innovation-models/cgt. Until such time additional data becomes available, we believe it is appropriate to map cases reporting the application of PZ to Pre-MDC MS-DRG 018 for FY 2025 based on the information currently available indicating similar utilization of resources for other cases currently mapped to MS-DRG 018 with regard to patients' severity of illness, treatment difficulty, and complexity of service.

In response to concerns that the assignment of new, higher volume, lower cost therapies to MS-DRG 018 could potentially distort the relative weight of the MS-DRG resulting in inadequate payment for CAR T-cell therapies, we note that in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48807), we addressed similar comments and also noted that we provided detailed summaries and responses to these same or similar comments in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798 through 44806). We also refer the reader to the discussion in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36018 through 36020), and in section II.D.2.b. of this final rule, regarding the proposed and finalized relative weight methodology for cases mapping to Pre-MDC MS-DRG 018 effective October 1, 2024, for FY 2025. After consideration of the public comments we received, we are finalizing our proposal to maintain the existing title to Pre-MDC MS-DRG 018, "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies" for FY 2025. We are also finalizing the assignment of the eight procedure codes describing the use of PZ to Pre-MDC MS-DRG 018 as reflected in Table 6B. – New Procedure Codes, in association with this final rule and available on the CMS website at https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps. (pp. 75-77)

Additional New Mapping to MS-DRG 018:

- Obecabtagene Autoleucel (Autolus)
- Orca-T Allogeneic T-cell Immunotherapy (Orca Bio)
- Non-Chimeric Antigen Receptor T-cell Immunotherapy (general code)

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Source: Table 6B, FY 2025 Supporting Tables and Files: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page

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

Section 108 Implementation

Update Medicare Advantage (MA) Payment Methodologies

MA plans that rely on CMS' MS-DRG methodology have been inconsistent in recognizing separate cost-based reimbursement for donor search cell and acquisition costs pursuant to Section 108. Since implementation of Section 108 is still relatively new, MA plans may lag behind in their understanding and implementation. Therefore, ASTCT once again requests that CMS communicate to MA plans that they should update contracts proactively in future contract negotiation and payment discussions with hospitals, which will reduce hospital burden and promote fair payment.

ASTCT requests that CMS instruct MA plans to update their payment methodologies to provide cost-based reimbursement for donor search and cell acquisition costs for allogeneic SCT as of Section 108's effective date.

CMS Response: CMS did not respond to this request.

Update instructions related to cost-reporting instructions associated with Section 108

There has been a significant delay in CMS' issuance of the cost reporting instructions associated with Section 108. Although the legislation was passed in December 2019, the final cost reporting instructions were not available until late 2022, and cost reporting software updates were not finalized until early-2023.

We have heard from hospitals that the current instructions need clarification in a few areas, including:

- Worksheet D-6: the instructions are not explicit that the donor charges are apportioned between inpatient and outpatient based on the status of the recipient when the patient received the transplant.
- Cost center 0077: CMS' instructions do not specify that the charges for cost center 0077 should be limited to the 0815 revenue code charges for purchased donor services and donor search performed by the hospital when direct costs are reported in cost center 0077.

ASTCT requests that CMS update and clarify its cost-reporting instructions associated with the implementation of Section 108 for these issues.

CMS Response: CMS did not respond to this request.

Implement a Medicare Code Editor edit for revenue code 0815

In the FY 2024 Proposed Rule, CMS asked for comments on what types of edits should be included in the Medicare Code Editor.[34] ASTCT requested that CMS implement an edit for claims with allogeneic ICD-

[34] CMS. FY 2024 IPPS Proposed Rule. Online: https://www.govinfo.gov/content/pkg/FR-2023-05-01/pdf/2023-07389.pdf p.95

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10-PCS codes that group to MS-DRG 014. This edit should reject claims when an inpatient type of bill 11X claim is received without charges greater than $0 billed under revenue code 0815, which is intended to capture the costs of donor search and cell acquisition activities for alloHSCT.

Mandatory reporting of the revenue code on inpatient claims will have several benefits. It will help ensure that transplant centers provide accurate claims reporting to CMS, mirror the edit in place in the OCE, ensure the accuracy of CMS' budget neutrality calculation, and ensure that CMS does not inappropriately generate outlier payment on MS-DRG 014 claims as CMS removes costs associated with revenue code 0815 from its outlier calculation.

ASTCT asks CMS to implement this MCE edit with the release of the FY 2025 IPPS final rule.

CMS Response: *We appreciate the commenter's feedback. As stated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58789), we may consider provider education materials regarding the reporting of Allogeneic Stem Cell Acquisition/Donor Services in the future. We continue to believe that the suggested claims processing edit is not necessary at this time and expect providers to appropriately report charges associated with revenue code 0815.* (p. 60)

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

ASTCT has significant concerns with CMS' NTAP proposal for the HSC gene therapies mapped to MS-DRGs 016 and 017. These concerns are summarized in the NTAP section earlier in this letter.

ASTCT requests that CMS utilize NTAP dollars and Value Code 90 to provide cost reimbursement for gene therapy products during the 2-3 year NTAP time frame while developing a longer-term payment mechanism.

CMS Response: See section on NTAP for SCD gene therapies earlier in letter.

Absence of Medicare Advantage Claims from IPPS Rate-Setting

In our FY 2024 Proposed Rule comment letter, ASTCT requested that CMS study the potential impact of MA shadow claims on rate-setting.[35] CMS responded with the following statement in the 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.*[36]

While CMS does not specifically mention MA data, the IPPS PR is focused on rate-setting methodology and, since the absence of MA data from rate-setting impacts MS-DRG base payments, ASTCT views this topic as being within scope of this comment letter.

[35] ASTCT Policy Letters and Statements. FY 2024 IPPS Proposed Rule Comment Letter. Online: https://www.astct.org/Advocacy/Policy-Letters-and-Statements
[36] CMS. FY 2024 IPPS Final Rule. Online: https://www.govinfo.gov/content/pkg/FR-2023-08-28/pdf/2023-16252.pdf, p. 20

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Based on recent CMS data, more Medicare beneficiaries (50%+) are now enrolled in MA plans than in traditional Part A and Part B plans.[37] The Congressional Budget Office (CBO) has predicted that the percentage of FFS beneficiaries enrolled in MA plans will grow to more than 61% by 2032.[38]

MA enrollment varies significantly across the United States, with substantially higher enrollment on the East and West coasts, the populous Southern states (e.g., Texas, Tennessee, Georgia, and Florida), and the upper Midwest (e.g., Michigan, Minnesota and Wisconsin).[39] This variation means that the FFS claims that Medicare utilizes for rate-setting are becoming cumulatively less representative of the national population's distribution, along with the hospitals that serve that population. Additionally, the states where MA enrollment is the highest (and therefore where FFS enrollees are the fewest) are also the states where there are likely to be the most academic medical centers and specialized hospitals, which are historically the fastest adopters of new therapies for rare and complex diseases.

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. *In the FY 2022 MedPAR data utilized for FY 2024 IPPS rate-setting, there were at least 390 MA CAR-T claims—an amount that would have increased the total volume used for rate-setting by 50%. Similarly, there were more than 1,600 MA SCT claims, which would have increased the collective total volume used for rate-setting by 36%.*[40]

Given the geographical disparities in MA enrollment, FFS claims from a limited number of centers in certain geographic areas of the country will drive an increasing proportion of the rate-setting data, even though they may further skew the IPPS resource calculations. Furthermore, most MA plans utilize IPPS MS-DRG base payments as the basis for payment to hospitals for MA beneficiaries, and hospitals must accept FFS rates for MA enrollees seeking care out of their plan's network. For the reasons stated above, it is not logical to use a set of claims that is no longer nationally representative to establish payment rates for treating both FFS and MA beneficiaries.

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 CMS as 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.[41] CMS already has access to the data it needs to examine the effect of MA inclusion on these issues, as 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 that CMS 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.

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[37] Fuglesten Biniek J, Freed M, Damico A, Neuman T, *Half of All Eligible Medicare Beneficiaries are Now Enrolled in Private Medicare Advantage Plans*, Palo Alto (CA): KFF, May 1, 2023: https://www.kff.org/policy-watch/half-of-all-eligible-medicare-beneficiaries-are-now-enrolled-in-private-medicare-advantage-plans/.
[38] Freed M, Fuglesten Biniek J, Damico A, Neuman T, *Medicare Advantage in 2022: Enrollment Update and Key Trends*, Palo Alto (CA): KFF, August 25, 2022: https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/.
[39] Ibid.
[40] CMS MedPAR Hospital National Limited Data Set, FY 2022
[41] CMS.gov. FY 2023 IPPS Final Rule. August 10, 2022. https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-16472.pdf, p. 75

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CMS Response: CMS did not respond to this request.

MS-DRG Methodological Issues and Coding

Market Basket Update

CMS' proposal to increase the market basket by 2.6% (after it accounts for a -0.4% productivity adjustment) is woefully inadequate to address rising hospital supply chain costs and will harm hospitals if finalized. ASTCT is deeply concerned that CMS proposes a much lower update factor than the 3.1% it finalized for FY 2024, given that hospitals continue to face staggering labor shortages, significant staff salary costs, high drug and supply expenses. These factors, taken together with hospitals' existing quality reporting and safety and accreditation requirements, adds to providers' overall uncompensated burden.

ASTCT requests that CMS finalize a market update basket factor that is at least equal to that finalized for FY 2024 (3.1%).

CMS Response: *CMS finalized a market basket update of 3.4% but this was reduced by a 0.5% productivity adjustment for a net increase of 2.9%. Source: FY 2025 IPPS FR Fact Sheet*

Delay of Proposed CC/MCC Split Criteria

ASTCT thanks CMS for the continued publication of the CC/MCC data to help evaluate the impact of these changes on providers. We continue to believe that the impacts to providers will be significant and potentially disruptive, given that the split would collapse and eliminate multiple MS-DRGs.

ASTCT supports CMS' proposal to continue delaying the application of its proposed CC/MCC split criteria for at least another fiscal year.

CMS Response: *After consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to delay the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2025 as we continue to consider the public comments received in response to the FY 2024 rulemaking.*

MDC 17 – Myeloproliferative Diseases & Disorders, Poorly Differentiated Neoplasms

In the proposed rule, CMS describes its analysis of MS-DRGs within MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms) and issues a number of proposals related to a reorganization of this MDC based on the analysis results.

The proposals include:

- Remapping chemotherapy cases with a secondary diagnosis of acute megakaryoblastic leukemia or panmyelosis with myelofibrosis;
- Adding ICD-10-PCS codes describing certain bypass procedures from the cerebral ventricle to the subgaleal space or cerebral cistern to certain MS-DRGs in the MDC;
- Creatring a new surgical base MS-DRG for acute leukemia cases with other procedures; and
- Removing Major OR procedures from the title of MS-DRGs 802, 821, and 822.

ASTCT appreciates that CMS continues to analyze and refine this MDC and that the agency recognizes the increased resource intensity involved in acute leukemia cases with certain operating room procedures.

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We support the changes that CMS has proposed for the reorganization of MDC 17, particularly the creation of the proposed MS-DRG 850, acute leukemia with other procedures; we ask CMS to finalize these changes as proposed.

CMS Response: This was finalized. See pp. 208-224 for full discussion.

Mapping and CC Status of *Lymphoma, In Remission* Codes

ASTCT supports CMS' proposed MS-DRG mappings for the newly created ICD-10-CM diagnosis codes for the different types of *lymphoma, in remission*. Specifically, CMS has proposed to assign a CC status to these codes. ASTCT agrees with this proposal, since patients with these diagnoses are generally more complex and resource-intensive, warranting assignment to a CC MS-DRG.

ASTCT requests that CMS finalize these proposals for FY 2025.

CMS Response: This was finalized in Table 6A accompanying the final rule.

Social Determinants of Health Codes

ASTCT supports CMS' ongoing review of Social Determinant of Health (SDOH) diagnosis codes, to identify which SDOHs may require a higher severity status within the MS-DRG system. We appreciate CMS' proposal to increase the severity level of the ICD-10-CM diagnosis codes identifying housing instability, to CC status.

We agree with this proposal and urge CMS to finalize this designation change for FY 2025.

CMS Response: *After consideration of the public comments received, we are finalizing changes to the severity levels for diagnosis codes Z59.10, Z59.11, Z59.12, Z59.19, Z59.811, Z59.812, and Z59.819, from NonCC to CC for FY 2025, without modification. In addition, these diagnosis codes are reflected in Table 6J.1 – Additions to the CC List—FY 2025 associated with this final rule and available at: https://www.cms.gov/medicare/payment/prospective-paymentsystems/acute-inpatient-pps. We refer the reader to section II.C.12.d of the preamble of the proposed rule and this final rule for further information regarding Table 6J.1*

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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