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Transplantation and Cellular Therapy

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

May 23, 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.

ASTCT is a professional membership association of more than 3,900 physicians, scientists, and other health care professionals promoting blood and marrow transplantation 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-based gene therapies for genetic immune system and blood disorders.

For more than 25 years, ASTCT members have focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases. ASTCT members very much rely on team care to treat the complex cancers and other disorders that require hematopoietic stem cell transplants (HSCTs) and newer cell therapies like CAR-T.

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

Corey Cutler, MD, MPH
President, ASTCT

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Executive Summary

ASTCT appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the FY 2025 Inpatient Prospective Payment System (IPPS) Proposed Rule; the following points are a summary of issues discussed, and recommendations provided, in more detail throughout the letter.

1. **Fixed-Loss Threshold**
   - The outlier fixed-loss threshold has now reached an excessive and extremely problematic level. ASTCT encourages CMS to review methodological changes to improve base MS-DRG payment rates which would facilitate a decrease in the number of cases that pull from outlier dollars on a routine basis.

2. **New Technology Add-on Payment (NTAP)**
   - ASTCT believes that the 75% NTAP proposed for the hematopoietic stem cell (HSC) gene therapy products for the treatment of sickle cell disease (SCD) is insufficient and will not support beneficiary access. ASTCT proposes an alternate use of NTAP dollars for cost reimbursement of these products.
   - ASTCT supports CMS' proposal to move the three-year NTAP anniversary date from April 1 to October 1 for the FY 2026 cycle.

3. **MS-DRG 018: Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies**
   - ASTCT recommends that CMS mitigate charge compression for MS-DRG 018 cases by utilizing the "other" cost-to-charge ration (CCR) to reduce CAR-T product charges to cost starting in FY 2025. The agency should utilize this method until CMS implements an alternative payment solution that results in a more appropriate base payment amount.
   - ASTCT supports maintaining the current title; we request that CMS not map prademagene zamikeracel to MS-DRG 018 due to the clinical resource differences between it and the other therapies that are currently mapped to this MS-DRG.

4. **MS-DRG 014: Allogeneic Bone Marrow (Stem Cell) Transplantation**
   - ASTCT recommends that CMS instruct MA plans to update their payment methodologies to provide cost-based reimbursement for donor search and cell acquisition costs for allogeneic HSCT as of the effective date of Section 108.
   - CMS should also update and clarify cost report instructions for Section 108
   - The agency is urged to implement a Medicare Code Editor edit that rejects claims reported with an allogeneic ICD-10-PCS code and without revenue code 0815 reported with charges greater than $0, similar to the long-standing outpatient edit in the Outpatient Code Editor.

5. **MS-DRG 016 & 017: Autologous Bone Marrow Transplant with and without CC/MCC**
   - ASTCT recommends that CMS utilize NTAP dollars and Value Code 90 to provide cost reimbursement for HSC gene therapy products during the 2-3 year NTAP time frame while it develops a longer-term payment mechanism (see NTAP section).

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6. **Absence of Medicare Advantage (MA) Claims from Rate-Setting**
   - ASTCT requests that CMS model the inclusion of MA shadow claims on MS-DRGs to understand the impact excluding these data have on case volume and rate-setting now that > 50% of Medicare beneficiaries receive their health care through MA plans.

7. **MS-DRG Methodological issues and Coding:**
   - ASTCT is concerned that the proposed market basket increase of 2.6% is woefully inadequate to address the significant staffing, drug, and supply costs that hospitals have faced and will continue to grapple with.
   - ASTCT supports CMS' proposal to delay implementation of the Complications and Comorbidities (CC) and Major Complications and Comorbidities(MCC) split criteria.
   - ASTCT supports CMS' proposals associated with MDC 17, including the creation of a new surgical base MS-DRG (850) for select acute leukemia cases.
   - ASTCT supports CMS' mapping and CC status proposals for the newly created *lymphoma, in remission* codes.
   - ASTCT supports CMS' ongoing review of the Social Determinants of Health Codes and its proposal to increase the severity level of the ICD-10-CM diagnosis codes that indicate housing instability.

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, by design, forces a 20% loss, since Medicare only pays 80% of the excess cost. Coupled with a growing fixed-loss threshold of almost $50,000 for each case, these losses are of significant financial concern, especially given the American Hospital Association's (AHA) recent report that Medicare pays hospitals approximately 82 cents on the dollar.[1] 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 this rise in the fixed-loss threshold not just because of the cell therapy (MS-DRG 018) and stem cell transplant (MS-DRG 016 and 017) cases that we treat that typically generate significant outlier dollars, but also because of the other MS-DRGs that our clinician's hospitals treat that have far lower payment rates; including DRGs within MDC 17 – Myeloproliferative Diseases and Disorders, which encompass many of the treatments for leukemia and lymphoma. These cases are high volume for hospitals and are now even less likely to receive outlier dollars, given the expected $50,000 loss before receiving the 80% marginal payment.

While CMS discusses some 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. The large percentage of MS-DRG 018 cases that receive an outlier payment indicates that the base payment is insufficient. It also underscores the point that ASTCT has been raising for years: that systematic charge compression issues associated with the development of the base payment is (and has been) very problematic for cases involving high-cost cell and gene therapy products. We note that these same drug charge compression issues will be amplified for any cases involving one of the newly approved HSC gene therapies, given their multimillion-dollar price points.

ASTCT requests that CMS carefully study how to slow the growth in the fixed-loss threshold. Additionally, we believe that CMS should 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 for more details).

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 sickle cell disease (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 (lovo-cel; Lyfgenia™) with a list price of $3.1 million.[2,3]

[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
[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/

ASTCT's members include physicians and hospitals that were intimately involved in the clinical development of these new therapies. They were diligent in every aspect related to the science and care for the clinical trial patients who made these approvals possible. Our members are eager to provide these new HSC gene therapies to the individuals and families who have been anxiously awaiting their turn for a functional cure.

As providers to individuals with blood cancers and disorders, we are frustrated and confused as to why the NTAP proposal and CMMI's new Model only apply to SCD, wthen the approved therapies also apply to TDT, have the same pricing and access concerns as SCD, and would benefit TDT patients, who have no other curative alternatives outside of an allogeneic HSCT (for certain patients). We will focus our comments primarily on SCD for the purpose of this comment letter but ask CMS to reconsider the limited focus of its proposals.

In response to the FDA approvals, the Centers for Medicaid & Medicare Innovation (CMMI announced, in February 2024, that it would focus the efforts of its new Cell and Gene Therapy (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."*[4] While the Model still needs to be operationalized and evaluated for health system impact, the unique methodology is both unprecedented and highly justified, given the severe health burden and lack of therapeutic options for people living with severe SCD.

In stark contrast to the Model, CMS makes only a token payment policy proposal for these SCD therapies for Medicare fee-for-service (FFS) and dual-eligible beneficiaries in the FY 2025 IPPS Proposed Rule. CMS proposes to increase the standard New Technology Add-on Payment (NTAP) maximum amount from 65% to 75%, which effectively resolves almost nothing from a hospital financial perspective, which discussed in more detail below.

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 handling payment for novel therapies such as HSC gene therapies, despite stakeholders having provided many ideas in the past. Moreover, CMS risks creating a two-class system by fostering innovation for Medicaid patients via CMMI while offering no solutions for traditional Medicare FFS or dual eligible patients with SCD or TDT.

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

ASTCT acknowledges the challenges facing CMS in an era of rapid medical innovation, rising costs, and growing numbers of beneficiaries and wishes to express our genuine appreciation for the partnership CMS has shown in the development and evolution of MS-DRG 018. Specifically, CMS sought 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. This is in stark contrast to what the agency has proposed for HSC gene therapies. ASTCT recognizes that CMS was unlikely to propose significant MS-DRG or IPPS changes prior to these therapies receiving FDA approval. But, we are concerned that approval was granted in December 2023, well before the FY 2025 IPPS Proposed Rule

[4] CMS. Cell and Gene Therapy Access Model. https://www.cms.gov/priorities/innovation/innovation-models/cgt

was released, yet CMS has not proposed any novel solutions in the Proposed Rule. Finally, ASTCT also acknowledges that these therapies' prices are beyond what would have been predicted when the IPPS system was designed, which is why it has been clear to us for years that a solution beyond the usual changes in the NTAP cap would be necessary

The policy proposal that CMS offers does nothing to address the series of ***compounding losses for hospitals****:* a low base 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 cumulative losses directly obstruct Medicare patients' access to gene therapies at their current prices because the absolute dollars lost at each juncture of the stacking payment methodology is cumulatively untenable. Finally, we note that the therapies' prices are beyond the control of the provider community and there are no effective lower-cost alternatives. Yet it is unacceptable for hospitals to have to choose between not providing these therapies or bearing enormous losses to do right by their patients.

Therefore, ASTCT recommends CMS implement the following recommendations 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.**
- **Require Medicare Administrative Contractors (MACs) to issue documentation confirming that these therapies will be covered per the FDA label.**
- **Do not make NTAP (including our alternate cost reimbursement proposal outlined below) for these therapies contingent on their participation in other pricing arrangements for the FY 2025 IPPS cycle (including our cost reimbursement proposal outlined below).**
- **Expand the proposal's limited focus and include TDT patients, as well.**

Modifying CMS' NTAP proposal will enable CMS to foster beneficiary access while the agency develops a better approach to MS-DRGs and IPPS payment for novel therapies in cases where the product cost significantly outweighs the patient care cost. This temporary solution is necessary to create parity with CMMI's innovative work and to generate better data for future DRG creation and rate-setting. We describe our methodological recommendation and the rationale for it in greater detail below.

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. CMS can use the following methodology to operationalize our request:

- Require hospitals to use value code 90 to report the product acquisition cost.
- CMS to 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—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.

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. 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).*[5]

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

[5] 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

Significant disparities between CMS' Medicaid and Medicare proposals

As noted, CMMI's CGT Access Model only applies to Medicaid beneficiaries. Medicare-FFS and Medicaid-Medicare dual-eligible individuals are not included in the Model and will not benefit from expanded access. But, 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.

This 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:

> *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.*[6]

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 the Department of Health & Human Services' (HHS) commitment to supporting their availability:

> *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.*[7]

As noted above, it is, therefore, disappointing that the CGT Access 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*

[6] 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

[7] 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

> *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.*[8]

By CMS' own estimates, in 2016, there were 11,790 Medicare beneficiaries with SCD, more than 70% of whom were dual-eligible and the majority of whom were non-elderly.[9] While the current total number of Medicare beneficiaries with SCD and the subset of that group who may be individually eligible for these therapies is unknown, one can reasonably assume there are Medicare beneficiaries who would be interested in and eligible for these therapies. **ASTCT does not view CMS' single FY 2025 IPPS proposal to slightly increase the NTAP dollars for which hospitals may be eligible as being in harmony with the level of attention and effort being put into the CMMI model.**

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.*** *(FY 2025 IPPS PR, pp. 455-456)*

Implemeting ASTCT's recommended methodology, CMS would not pay more for a product than the hospitals did to acquire it. 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. 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 patients for the expected 3-6 week administration hospitalization.[10,11]

[8] 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
[9] 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
[10] Lygenia.com. Your Lygenia FAQs answered. Accessed May 2, 2024. Online: www.lyfgenia.com
[11] Casgevy.com. A guide to your treatment journey. Accessed May 2, 2024. Online: www.casgevy.com

Additionally, as the AHA noted in a prior letter to CMS, the agency has not typically fully spent the pool of NTAP dollars it allocates.[12]

Requiring hospitals to mark-up multimillion dollar products is highly problematic in an era of price transparency and it is also 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. Additionally, 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 from a mathematical perspective 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 in an era of required price transparency, and lack of knowledge by the press, consumers, and others who disparagingly write about hospital charging practices without having any understanding of CMS' payment formulas that require this level of charging – not to break even, but just to lose less money. Our members have expressed 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.

From a methodological perspective, CMS' typical practice of developing a case-weight product cost when it considers two NTAP applicants to be substantially similar will not assist with these issues. In the past, when CMS finalized an NTAP for substantially similar products, the agency has utilized a weighted average of the product costs to calculate the dollar amount that would be eligible for NTAP payment.[13] If CMS applies this same methodology—and 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.[14]

Yet, 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, a difference of ***$800,000***, not a few hundred or thousand dollars as has been the case with past products. As a result, 75% of the potential case-weighted $2.65 million product cost will not enable hospitals to alternate products and average the NTAP payments. As a result of the way that NTAP is calculated and paid with a lesser-of formula, an individual product cost billed against the 75% threshold for a case-weighted average product cost will still result in massive losses for providers.

To implement ASTCT's recommendation, CMS can exercise its 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, " enabling it to implement ASTCT's recommendation.

[12] 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
[13] 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
[14] 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

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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. This model demonstrates that even hospitals that charge appropriately for these therapies (e.g., by marking up the product cost to develop a charge in accordance with their overall operating and capital CCRs) and receive the maximum 75% NTAP amount proposed will still face a significant financial loss.

In this model, we assume that, with the exception of having very different mark-up practices that impact the gene therapy product charge, all other parameters are identical between the two facilities; specifically, both Hospital A and B:

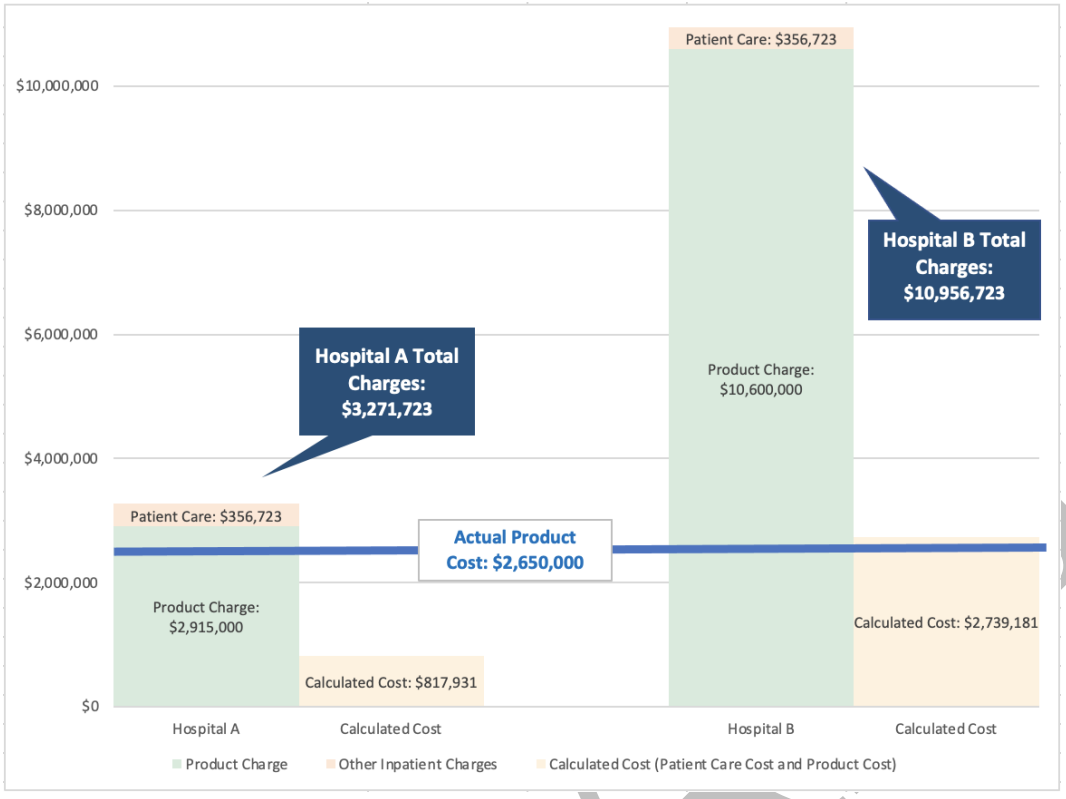
- Certified by both manufacturers to provide their HSC gene therapies for SCD;
- Pay the manufacturer $2.65M to acquire the product (this amount is an average of the two commercially approved product prices, for simplicity's sake);
- Have a wage index of 1.0 and no other hospital-specific adjustments to their MS-DRG payment;
- Have an overall CCR of 0.25;
- Have a 30-day inpatient stay during which the autologous HSC gene therapy is administered and have identical patient care charges.[15]

The only difference between Hospital A and B is how they apply a mark-up to the gene therapy product cost: Hospital A applied a 1.1x mark-up (i.e., its standard 10% policy) to the $2.65M product cost, while 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 it multiplies total covered claim charges by the hospital's own overall operating and capital CCRs.

As shown in the light orange bar below, CMS' calculated cost for Hospital A has absolutely no bearing to the actual cost incurred by Hospital A.

[15] 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.


$10,000,000
$8,000,000
$6,000,000
$4,000,000
$2,000,000
$0
Patient Care: $356,723
Product Charge: $2,915,000
Calculated Cost: $817,931
Actual Product Cost: $2,650,000
Hospital A Total Charges: $3,271,723
Patient Care: $356,723
Product Charge: $10,600,000
Calculated Cost: $2,739,181
Hospital B Total Charges: $10,956,723
Hospital A
Calculated Cost
Hospital B
Calculated Cost
Product Charge
Other Inpatient Charges
Calculated Cost (Patient Care Cost and Product Cost)

CMS uses what it computed as the case cost in order to determine NTAP and outlier payments. This results in very different overall payments to both hospitals as shown in the chart below:

- Hospital A does not reach the 75% proposed NTAP cap that is available for cases that would use the HSC SCD-indicated gene therapy products.
- Hospital A does not have residual additional costs and, therefore, does not trigger any outlier payment.
- Hospital B does reach the 75% proposed NTAP cap of $1,987,500 (assuming that the new technology cost cap is based on averaging the two approved product costs together to achieve the $2.65M product cost used in the example)
- Hospital B has residual cost which results in an outlier payment.

The combination of the MS-DRG 016 FY 2025 proposed unadjusted payment amount, the full NTAP capped payment amount, and the additional outlier payment results in a calculated total payment of $2,558,069 for Hospital B. *This means that the overall total Medicare reimbursement—even for a*

hospital that charges appropriately and can access the full proposed 75% NTAP cap—is less than the cost that the hospital paid for the HSC gene therapy product. It provides no additional dollars to pay for the inpatient stay required to deliver the therapy to the patient.

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.

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 they set their charges appropriately, hospitals are likely to come up short on the product acquisition cost alone, even before factoring in the costs of the intensive clinical care delivered during the extended inpatient episode. These issues, in combination with multimillion dollar product prices, mean that hospitals are faced with only bad choices and even worse financial outcomes.

If implemented, ASTCT's proposed solution would enable CMS to side-step the current methodological challenges and promote access while the agency works with stakeholders to develop a more sustainable long-term payment structure for cell and gene therapies where 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 act and put forth a solution that holds providers harmless and enables patients to access needed care from clinicians and hospitals that want to provide it.

Finally, we note that there are only a limited number of centers approved by manufacturers to administer these gene therapies. The processes of collecting cells, manufacturing individual products, and administering them are complex and lengthy—the patient journey descriptions for these products depict a minimum time frame of 7-8 months per person.[16,17] Manufacturers' public-facing statements support the fact that only a limited number of patients will be treated; in recent guidance, bluebird bio estimated between 85-105 patient "starts" for lovo-cel in all of 2024.[18] 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.

Limited NTAP budget impact and avoidance of extreme outlier payments

As noted elsewhere in this comment letter, ASTCT members are extremely concerned with the rapid growth and increasingly upward trend of the fixed-loss outlier threshold. In a theoretical situation where hospitals still move forward with treatment despite the huge negative financial impact expected if CMS only implements a 75% NTAP, these SCD cases will be paid in large part through outlier dollars, as shown in our Hospital A and B example above. While the total volume of these cases would be relatively

[16] 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
[17] Lyfgenia.com. Steps to Treatment. Accessed May 15, 2024. Online: https://www.lyfgenia.com/sickle-cell-treatment-journey
[18] 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

minimal, they have the potential to pull a cumulatively significant amount of outlier dollars, thereby increasing the likelihood of further driving up the fixed-loss threshold for all cases in future years.

Developing data for future rate-setting

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 almost assuredly need to create a new MS-DRG 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, and creating a severe underpayment situation for cases using an HSC gene therapy.

Adopting ASTCT's alternate NTAP proposal will preserve access to these therapies. It will also provide CMS with claims data (which it prefers to use in rate-setting) to use to develop a future payment model. These claims data include information on:

- Case volume and costs: While these cases will likely be cumulatively low-volume for the foreseeable future, the ASTCT proposal supports access and will accrue 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 data: Like CAR-T, these cases are unusual for the PPS payment and rate-setting framework, since the product acquisition costs are many multiples of clinical care costs, and since providers have limited bargaining power over individualized product costs. Using the value code will allow CMS to track the price at which hospitals purchase the gene therapies. If hospitals can negotiate a discount, participate in some aspect of the CMMI program, or benefit from a Medicare drug negotiation program, CMS will have access to those data. It can then learn how best to account for product acquisition costs as the agency builds out a post-NTAP durable payment mechanism.

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 requested 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 within the MS-DRG structure, noting that it will evaluate stakeholder suggestions for future rulemaking.

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 methodologies, logic, and decision-making precedents. In addition to comments submitted during the public comment periods for each rule, ASTCT has also submitted extensive proposals during the DRG modification comment period that occurs each Fall. In our communication, 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 formulas, charge compression and future rate-setting, and the need for novel solutions in an era of novel therapies.

Over 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 *ex vivo* 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.
- Utilize a "bridge" CCR (the "other" CCR) as CMS works toward more accurate development of MS-DRG base payment rates.

Given the wealth of input provided to CMS, ASTCT expected the agency to evaluate the options provided and include some rationale in this proposed rule for not pursuing any of them and, instead, for proposing a modest increase to the NTAP cap for HSC gene therapies. We are genuinely perplexed by the agency's lack of engagement with the stakeholder community on these issues as it is out of step with what the agency has been seeking input on for years. 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.

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.* (p. 456)

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 efforts to negotiate these types of arrangements for the CMMI project 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 their participation in other pricing arrangements for the FY 2025 IPPS cycle.

Hospitals need confirmation of coverage for gene therapy

Separate from payment policy proposals, CMS has yet to clarify national coverage for the gene therapies for Medicare beneficiaries or require MACs to issue local documentation in a timely manner. The following is listed in the CMMI model "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.*[19]

Hospitals are aware that these therapies are approved biologics that meet statutory requirements—i.e., they are part of a covered benefit category and performed as part of SCT, an inpatient hospital service that is reasonable and necessary for the treatment of an illness.[20] 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.

As previously noted, however, the products' acquisition costs 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, we believe, the vast majority of hospitals will be unwilling to take, 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."* [21] 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.

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

[20] 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

[21] 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

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

CMS proposes to amend the current practice of using April 1 as date for determining whether a newness anniversary date would qualify a technology for a potential third year of NTAP beginning in FY 2026. This is an important adjustment, given that the FDA changed its 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.

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.[22]

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

ASTCT appreciates that CMS continues to separate 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.

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

ASTCT continues to acknowledge that MS-DRG 018 is the highest-paying DRG in the IPPS system. We also continue to note that the primary driver of the high costs associated with this DRG is the product

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

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,[23] due to the significant charge compression that occurs (described in detail below).

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 indicate 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 an 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.

CMS' rate-setting methodology (e.g., applying the extremely low drug CCR to the pharmacy charges reported on MS-DRG 018 claims) significantly underestimates the CAR-T product cost. This comes as no surprise to ASTCT, since 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 and also drives the majority of the MS-DRG payment, it will be virtually impossible for CMS to create a payment rate based on provider billed charges. 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, as this is what CMS uses in its NTAP and outlier formulas to reduce billed charges to cost.

The reality is that CMS uses a completely different CCR for the purposes of rate-setting.[24] The drug CCR is 0.18, while the average operating and capital CCR of CAR-T hospitals is about .25. This mismatch is significant and will continue to result in an extreme percentage of cases receiving a substantial amount of their total payment from outlier dollars. Additionally, as cellular therapies expand to more hospitals, including those in low wage-index areas, they will receive even lower total reimbursement despite having the same product acquisition costs, and will rely 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.

We are not asking CMS to make this correction for *every* MS-DRG that involves high-cost drugs or biologics. Rather, we are asking CMS to create a threshold test such that, when more than X% 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* to provide fair payment that is more not less, reflective of the average cost of the case.

[23] CMS. FY 2022 IPPS Final Rule. Online: https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf (p.192)
[24] CMS. FY 2022 IPPS Final Rule. Online: https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf (p.192)

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."[25] 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, 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.

While the availability of outlier dollars is an important backstop for the IPPS system, it should not be relied upon as the primary source of payment for most cases within a single MS-DRG. By design, a hospital that receives an outlier payment has *already* 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.

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

> *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). For example, 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: *"[w]e'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*."[26]

Since then, 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

[25] 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/.
[26] U.S. Food and Drug Administration; FDA approval brings first gene therapy to the United States, August 2017.

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."*[27] 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.[28] 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 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. Because these therapies are person-specific and cannot be utilized for anyone else, no bulk purchasing discounts are available. And, as CMS knows, 340B rates are not eligible for inpatient hospital use.

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. 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. Nonetheless, providers find it very uncomfortable to establish extremely high gross charges for products that cost more than $400,000 when the applicable drug CCRs are very low. This, coupled with the small 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.

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.

[27] U.S. Food and Drug Administration; Establishment of the Office of Therapeutic Products, March 2023.
[28] National Uniform Billing Committee; New Cell/Gene Therapy Codes, September 2018.

Title Change and 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), 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 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 agrees with CMS' decision to not modify the current title of MS-DRG 018 based on a stakeholder's request.

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

Section 108 Implementation

Update Medicare Advantage 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 that MA plans 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.

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.

Implement a Medicare Code Editor edit for revenue code 0815

In the proposed rule, CMS asks for comments on what types of edits should be included in the Medicare Code Editor (MCE). ASTCT requests that CMS implement an edit for claims with allogeneic ICD-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 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.

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

ASTCT has significant concerns with CMS' proposal regarding 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.

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.[29] 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.*[30]

While CMS does not specifically mention MA data in this proposed rule, the IPPS is focused on rate-setting methodology; thus, we view the absence of MA data as being within scope.

ASTCT requests CMS examine and publish how including MA claims data would impact the IPPS rate-setting for certain MS-DRGs, particularly for MS-DRGs that are focused on high-intensity procedure-driven hospitalizations, like those mapped to pre-MDC MS-DRGs 014/016/017 and 018 for hematopoietic stem cell transplant and chimeric antigen receptor t-cell therapy, respectively.

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

Based on recent CMS data, more Medicare beneficiaries (50%+) are now enrolled in MA plans rather than traditional Part A and Part B, also known as Fee-for-Service (FFS) Medicare.[31] The Congressional Budget Office (CBO) has predicted that the percentage of beneficiaries enrolled in MA plans will grow to more than 61% by 2032.[32] This is a dramatically different beneficiary enrollment landscape than when CMS overhauled the DRG system and developed Medicare-severity DRGs in 2007, at which time the MA enrollment rate was just under 20%.[2]

MA enrollment varies significantly across the United States, with substantially higher enrollment on the coasts, the populous Southern states (e.g., Texas, Tennessee, Georgia, and Florida) and the upper Midwest (e.g., Michigan, Minnesota and Wisconsin).[2] This variation means that the FFS claims that Medicare utilizes for rate-setting are not only decreasing in total number (representing less than half of beneficiaries) but also 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 that were not included in rate-setting—an amount that would have increased the total volume by 50%. Similarly, there were more than 1,600 MA SCT claims that were not included in rate-setting, which would have increased the collective total volume by 36%.*[33]

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.

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 recommends that CMS model the inclusion of MA shadow claims on relative weights and share the findings with stakeholders for feedback in a future rulemaking cycle.

A higher volume of claims will make CMS' analyses of claims more statistically robust. It will 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

[31] 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/.
[32] 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/.
[33] CMS MedPAR Hospital National Limited Data Set, FY 2022

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 the 48854 FR IPPS 2023 FR.

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. Additionally, we request that CMS release all claims data used in the study, including data for both MA and FFS encounters, for independent stakeholder analysis.

MS-DRG Methodological Issues and Coding

Market Basket Update

CMS' proposal to increase the market basket by 2.6% (after it accounts for a minus .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, all in addition to our existing quality reporting and safety and accreditation requirements.

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

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 it 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.

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; the addition of 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; and the creation of a new surgical base MS-DRG for acute leukemia cases with other procedures (and the removal of 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.

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, and ask that CMS finalize these changes as proposed.

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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 since patients with these diagnoses are generally more complex and resource intensive and warrant assignment to a CC MS-DRG.

ASTCT requests that CMS finalize these proposals for FY 2025.

Social Determinants of Health Codes

ASTCT supports CMS' ongoing review of Social Determinant of Health (SDOH) diagnosis codes, to identify which SDOHs may warrant 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.

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