



American Society for  
Transplantation and Cellular Therapy

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](mailto:amaloney@astct.org).

A handwritten signature in black ink, appearing to read "C. Cutler", followed by a period.

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 (PR). The following points are a summary of our requests from throughout the letter.

### 1. Fixed-Loss Threshold

- The outlier fixed-loss threshold has now reached an excessive and extremely problematic level. ASTCT requests that CMS review methodological changes to improve base Medicare Severity Diagnosis-Related Group (MS-DRG) payment rates that 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 HSC gene therapy products used in the treatment of sickle cell disease (SCD) is insufficient and will not support beneficiary access. ASTCT requests that CMS implement our suggested alternate use of NTAP dollars for 100% 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 requests that CMS mitigate charge compression for MS-DRG 018 cases by utilizing the "other" cost-to-charge ratio (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 requests 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 requests that CMS instruct Medicare Advantage (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.
- ASTCT requests that CMS clarify and update cost report instructions for Section 108.
- ASTCT requests that CMS implement a Medicare Code Editor (MCE) edit that rejects claims reported with an allogeneic ICD-10-PCS code and with \$0 reported in revenue code 0815, similar to the long-standing outpatient edit in the Outpatient Code Editor.

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

- ASTCT requests 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 the agency 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 Pre-Major Diagnostic Categories (MDC) MS-DRGs to understand the impact that excluding these data has on case volume and rate-setting now that more than 50% of Medicare beneficiaries receive their health care through MA plans.

**7. MS-DRG Methodological Issues and Coding:**

- ASTCT asks CMS to increase the market basket update by at least 3.1%, as the current proposal is inadequate to address hospital costs.
- 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.



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## 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.<sup>1</sup> 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).**

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

<sup>1</sup> 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>

<sup>2</sup> 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>

<sup>3</sup> 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/>

<sup>4</sup> US FDA. Zynteglo. Accessed May 28, 2024. Online: <https://www.fda.gov/vaccines-blood-biologics/zynteglo>



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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.*”<sup>5</sup> 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 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.

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<sup>5</sup> CMS.gov. Cell and Gene Therapy Access Model. <https://www.cms.gov/priorities/innovation/innovation-models/cgt>



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*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.

## **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





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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.

## **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).<sup>6</sup>*

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.<sup>7</sup> 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.

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<sup>6</sup> 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>

<sup>7</sup> 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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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:

*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.”<sup>8</sup>*

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.”<sup>9</sup>*

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.”<sup>10</sup>*

**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**

<sup>8</sup> 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>

<sup>9</sup> 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>

<sup>10</sup> 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>

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.

***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.**<sup>11</sup>*

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.<sup>12,13</sup>

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

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<sup>11</sup> Proposed Rule, pp. 455-456.

<sup>12</sup> Lygenia.com. Your Lygenia FAQs answered. Accessed May 2, 2024. Online: [www.lygenia.com](http://www.lygenia.com)

<sup>13</sup> Casgevy.com. A guide to your treatment journey. Accessed May 2, 2024. Online: [www.casgevy.com](http://www.casgevy.com)

*\$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.

In addition to charging practice concerns, CMS' precedent 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.<sup>14</sup> 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.<sup>15</sup> 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 parameters 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.<sup>16</sup>

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).

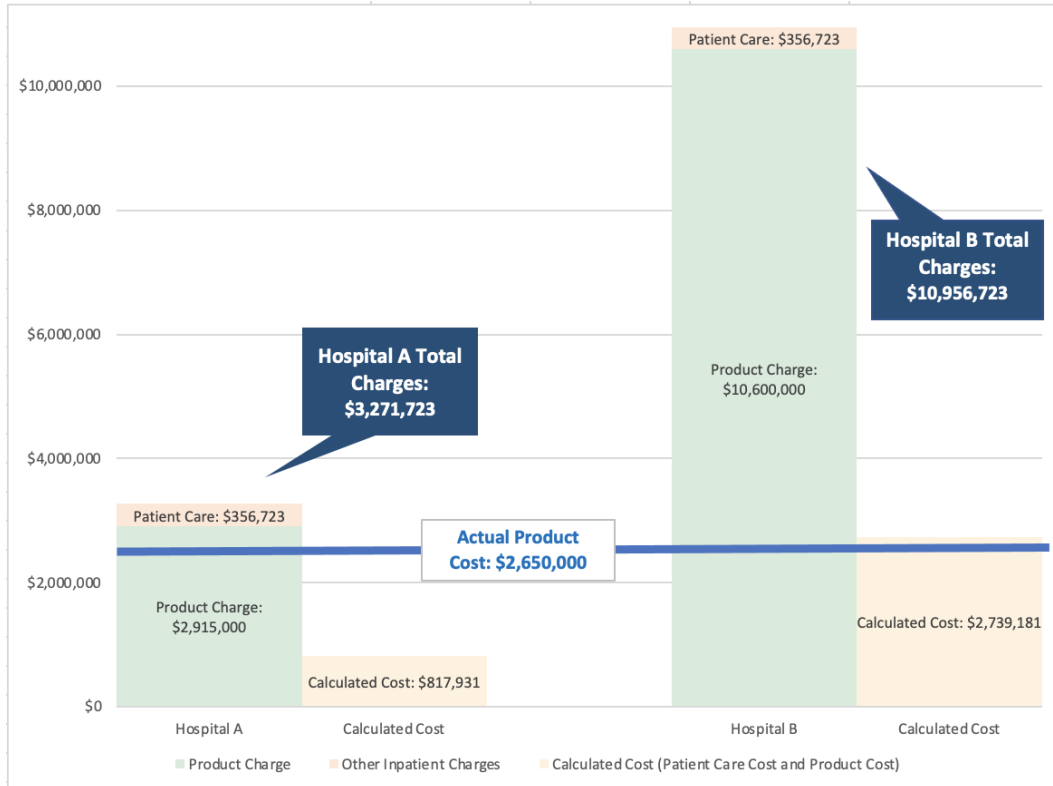
The result, as shown in the green bars below, is that the hospitals have very different product charges and, hence, very different total claim charges—*despite the fact that patient care charges are identical*. This leads CMS to compute a very different case cost estimate for each hospital when the agency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

<sup>14</sup> 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>

<sup>15</sup> 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

<sup>16</sup> 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.

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.



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.



- 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.<sup>17,18</sup> Last, manufacturers’ capacity is finite; as an example, bluebird bio estimated between 85-105 patient “starts” for lovo-cel in all of 2024.<sup>19</sup>

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.<sup>20</sup>

### *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.

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<sup>17</sup> Casgev.com. A Guide to Your Patient Journey. Accessed May 15, 2024. Online: [https://www.casgev.com/sickle-cell-disease/sites/default/files/treatment-journey-brochure-SCD\\_Desktop.pdf](https://www.casgev.com/sickle-cell-disease/sites/default/files/treatment-journey-brochure-SCD_Desktop.pdf)

<sup>18</sup> Lyfgenia.com. Steps to Treatment. Accessed May 15, 2024. Online: <https://www.lyfgenia.com/sickle-cell-treatment-journey>

<sup>19</sup> 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>

<sup>20</sup> 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.<sup>21</sup>*

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.**

## 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 Medicaid 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.**<sup>22</sup>*

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, an inpatient hospital service that is reasonable and necessary for the treatment of an illness.<sup>23</sup> 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

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<sup>21</sup> Proposed Rule, p. 456.

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

<sup>23</sup> 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>



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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.”*<sup>24</sup> 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.**

### **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.**

### **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.<sup>25</sup>

### **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

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<sup>24</sup> CMS.gov Newsroom. CMS Statement on Proposed Local Coverage Determination (LCD) for Skin Substitute Grafts/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>

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



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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 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 this letter, and in our comment letter on the FY 2024 IPPS Proposed Rule.<sup>26</sup> 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,<sup>27</sup> 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

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<sup>26</sup> ASTCT.org. <https://www.astct.org/Advocacy/Policy-Letters-and-Statements>

<sup>27</sup> CMS. FY 2022 IPPS Final Rule. Online: <https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf> (p.192)

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 the care they provided.<sup>28</sup> 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.

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.”<sup>29</sup> 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:<sup>30</sup>

*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*

<sup>28</sup> CMS. FY 2022 IPPS Final Rule. Online: <https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf> (p.192)

<sup>29</sup> 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/>.

<sup>30</sup> 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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*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 approved in August 2017, the FDA issued a press release in which then-FDA Commissioner Scott Gottlieb, MD, stated:

*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.<sup>31</sup>*

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."<sup>32</sup> 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.<sup>33</sup> 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.

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<sup>31</sup> U.S. Food and Drug Administration; [FDA approval brings first gene therapy to the United States](#), August 2017.

<sup>32</sup> U.S. Food and Drug Administration; [Establishment of the Office of Therapeutic Products](#), March 2023.

<sup>33</sup> National Uniform Billing Committee; [New Cell/Gene Therapy Codes](#), September 2018.





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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.

**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.**

### 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.**

## 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.**



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### *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 FY 2024 Proposed Rule, CMS asked for comments on what types of edits should be included in the Medicare Code Editor.<sup>34</sup> ASTCT requested 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 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.**

### **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.**

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



## 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.<sup>35</sup> 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.<sup>36</sup>*

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.

Based on recent CMS data, more Medicare beneficiaries (50%+) are now enrolled in MA plans than in traditional Part A and Part B plans.<sup>37</sup> 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.<sup>38</sup>

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).<sup>39</sup> 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%.<sup>40</sup>*

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,

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<sup>35</sup> ASTCT Policy Letters and Statements. FY 2024 IPPS Proposed Rule Comment Letter. Online: <https://www.astct.org/Advocacy/Policy-Letters-and-Statements>

<sup>36</sup> CMS. FY 2024 IPPS Final Rule. Online: <https://www.govinfo.gov/content/pkg/FR-2023-08-28/pdf/2023-16252.pdf>, p. 20

<sup>37</sup> 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/>.

<sup>38</sup> 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/>.

<sup>39</sup> Ibid.

<sup>40</sup> CMS MedPAR [Hospital National Limited Data Set](#), FY 2022



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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.<sup>41</sup> 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.**

## 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%).**

### 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.**

## 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

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<sup>41</sup> 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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- 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;
- Creating 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.

**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.**

#### **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.**

#### **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.**

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