



American Society for
Transplantation and Cellular Therapy

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

June 9, 2023

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: CMS-1785-P: Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit the following comments letter regarding the FY 2024 IPPS Proposed Rule.

The ASTCT is a professional membership association of more than 3,700 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 for the complex cancers and other disorders requiring hematopoietic stem cell transplants (HSCTs) and newer cell therapies like CAR-T.

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

A handwritten signature in blue ink that reads "M. A. P." followed by a horizontal line.

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Executive Summary

The ASTCT appreciates the opportunity to provide comments to CMS regarding the FY 2024 IPPS Proposed Rule; the following points are a summary of issues discussed, and recommendations provided, in more detail throughout the letter.

1. **FY 2024 is a critical time for cell and gene therapies**

- Explore strategies and create new proposals to address the flaws in the current IPPS payment process for novel cell and gene therapies and introduce payment innovation for cell and gene therapies.
- Seek stakeholder input on new payment policies for cell and gene therapies, such as by hosting a series of Town Hall meetings throughout FY 2024.

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

- Maintain the \$373,000 minimum standardized pharmacy charge as a filter to determine whether the CAR-T claim should be utilized for rate-setting to facilitate monitoring of claims data and impact on the relative weight.
- Mitigate charge compression for MS-DRG 018 cases by utilizing the “other” CCR to reduce CAR-T product charges to cost starting in FY 2024 as a strategy to address charge compression until CMS implements an alternative payment solution.

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

- Maintain cost-based reimbursement for donor search and cell acquisition for all allogeneic hematopoietic stem cell (alloHSCT) donor sources, including novel donor sources like omidubicel.
- Update Medicare Advantage (MA) payment methodologies and instruct MA plans to utilize cost-based reimbursement for donor search and cell acquisition costs for alloHSCT.
- Allow transplant centers at least 90 days to file cost reports under Section 108 and permit centers to amend any cost reports impacted by the delayed cost reporting instructions.
- Implement a Medicare Code Editor edit for claims with allogeneic ICD-10-PCS codes that group to MS-DRG 014, such that it will be rejected when an inpatient type of bill 11X claim is received without charges greater than \$0 billed under revenue code 0815.

4. **MS-DRG 016 & 017: Autologous Bone Marrow Transplant with and without CC/MCC**

- Address payment policies for HSC gene therapies that are assigned to MS-DRGs 016 and 017 by 1) establishing a new MS-DRG for autologous ex vivo HSC gene therapies for the FY 2025 cycle; 2) propose a new payment mechanism for acquisition of the HSC gene therapy products; and/or 3) explore inclusion of Medicare beneficiaries in CMMI’s proposed innovative payment models.

5. **General IPPS Provisions**

- New Technology Add-On Payments (NTAP)
 - Address the increased volume of NTAP applications by implementing new approaches to the NTAP annual cycle, including processing and vetting applications at least twice per calendar year.



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Executive Summary, continued

- Do not modify the FDA approval date requirement from July 1 to May 1, as it would further delay availability of NTAP payments for new technologies and services.
- Consider an alternative NTAP pathway for cell and gene therapies utilized in the IPPS, similar to the Qualified Infectious Disease Products (QIDPs) pathway, which would assist with the establishment of cell and gene therapies in the Medicare beneficiary population.
- Consider a standard third-year extension of NTAP for cell and gene therapies to address the unique manufacturing process and low-volume nature of the diseases treated.
- Growth in Medicare Advantage's impact on claims volume for rate-setting
 - Examine the effect of including Medicare Advantage shadow claims with FFS claims on
 - 1) rate-setting for rare diseases and procedures, such as the administration of CAR-T, and
 - 2) volumes utilized for establishing new and/or splitting current MS-DRGs.
 - Share the findings with stakeholders in an upcoming proposed rule.
- MEARIS System
 - Review the system to ensure that MEARIS can accept generalized comments and/or comments impacting more than a single MS-DRG.
- CC/MCC Criteria
 - Delay the application of CC/MCC Criteria to existing MS-DRGs until CMS provides an explanation of how the proposed changes are intended to improve the explanatory power of the MS-DRG system.

FY 2024 will be a critical time for cell and gene therapies

The wave of predicted innovation is no longer theoretical—FY 2024 will see record numbers of Medicare beneficiaries who clinically qualify for these life-changing treatments. An FDA decision regarding lifileucel, an immunotherapy mapped into MS-DRG 018, is expected early in the fiscal year¹ and two other manufacturers have indicated that their regulatory submissions are in process.^{2,3} Additionally, multiple hematopoietic stem cell-based *ex vivo* gene therapies for blood disorders like beta thalassemia and sickle cell disease have either been approved⁴ or are awaiting approval decisions within FY 2024.^{5,6} Unfortunately, the PPS hospitals that seek to provide these gene therapies as part of a stem cell transplant episode of care will face extreme reimbursement challenges in the IPPS setting, creating further access barriers for populations that CMS acknowledges have been historically underserved by the Medicare program.⁷ **New strategies are desperately needed; the traditional method of waiting for PPS claims data to accumulate will not work if the reimbursement barrier is so high that most hospitals will be unwilling to provide these treatments.** CMS must proactively act to implement innovations for the payment of novel cell and gene therapies.

Introduce Payment Innovation for Cell and Gene Therapies

The FY 2022 data used for the FY 2024 proposed rule contained the largest CAR-T case volume to-date, with 780 cases used for rate-setting. That number is, however, well below the estimated

¹ Iovance Biotherapeutics, “Press Release: Iovance Biotherapeutics Announces U.S. Food and Drug Administration Acceptance of Biologics License Application for Lifileucel for the Treatment of Advanced Melanoma,” May 26, 2023: <https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-us-food-and-drug>.

² Adaptimmune, “Press Release: Adaptimmune Reports First Quarter Financial Results and Business Update,” May 12, 2023: <https://www.adaptimmune.com/investors-and-media/news-center/press-releases/detail/245/adaptimmune-reports-first-quarter-financial-results-and>.

³ Atara Bio, “Press Release: Atara Biotherapeutics Announces First Quarter 2023 Financial Results and Operational Progress,” May 8, 2023: <https://investors.atarabio.com/news-events/press-releases/detail/316/atara-biotherapeutics-announces-first-quarter-2023>.

⁴ Bluebird bio, “Press Release: bluebird bio Announces FDA Approval of ZYNTGLO®, the First Gene Therapy for People with Beta-Thalassemia Who Require Regular Red Blood Cell Transfusions,” August 17, 2022: <https://investor.bluebirdbio.com/news-releases/news-release-details/bluebird-bio-announces-fda-approval-zynteglor-first-gene-therapy>.

⁵ Bluebird bio, “Press Release: bluebird bio Submits Biologics License Application (BLA) to FDA for lovotibeglogene autotemcel (lovo-cel) for Patients with Sickle Cell Disease (SCD) 12 years and Older with a History of Vaso-Occlusive Events,” April 24, 2023: <https://investor.bluebirdbio.com/news-releases/news-release-details/bluebird-bio-submits-biologics-license-application-bla-fda-0>.

⁶ Vertex, “Press Release: Vertex and CRISPR Therapeutics Complete Submission of Rolling Biologics License Applications (BLAs) to the US FDA for exa-cel for the Treatment of Sickle Cell Disease and Transfusion-Dependent Beta Thalassemia,” April 3, 2023: <https://investors.vrtx.com/news-releases/news-release-details/vertex-and-crispr-therapeutics-complete-submission-rolling>.

⁷ Centers for Medicare & Medicaid Services (CMS), *CMS Health Equity Blog - On the Path to Health Equity: Improving the Quality of Sickle Cell Disease Care*, Baltimore (MD): CMS, September 22, 2016: <https://www.cms.gov/About-CMS/Agency-Information/OMH/about-cms-omh/blog/sickle-cell-disease-care>.

number of Medicare beneficiaries who could benefit from CAR-T, which indicates that beneficiaries continue to face barriers to access. Even with a steady growth in cases across fiscal years, the recent volume gains are precarious—and the future remains unknown, as our members will enter FY 2024 without New Technology Add-on Payment (NTAP) being available for any CAR-T products, while they also face continued charge compression issues. While CAR-T is an important therapy for the ASTCT, it is only one of many innovative therapies that would potentially be provided by our member physicians and hospitals in the next few years—if all of these innovative therapies face similar rate-setting and payment issues, most of our member providers will face very difficult decisions about the future of this service line.

We recognize and appreciate that CMS has acknowledged the IPPS issues that are particularly acute for cell and gene therapies in multiple ways over the past several years:

- ***Rethinking resource use and complexity within MS-DRGs*** – FY 2020 Proposed Rule: “Given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. We may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10. We plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS– DRGs to better recognize complexity of service and resource utilization.” ([19230 FR FY 2020 IPPS Proposed Rule](#))
- ***Potential new Major Diagnostic Category (MDC)*** – FY 2022: “We plan to continue engaging with stakeholders on additional options for consideration in this field of cellular and gene therapies, such as the creation of new and distinct MS–DRGs and to determine if the creation of a new MDC may be warranted to which unique MS–DRGs could be established and the appropriate corresponding procedure codes could be proposed for assignment.” ([44806 FR FY 2022 IPPS Final Rule](#))
- ***Stakeholder engagement*** – FY 2021: “Finally, amidst our work on payment accuracy and coverage for CAR-T, we have heard from stakeholders that cell therapy goes beyond CAR-T to include Tumor-Infiltrating Lymphocyte (TIL) Therapy and Engineered T Cell Receptor (TCR) Therapy. While all of these treatments are autologous, CAR-T is currently limited to liquid tumors, and we foresee the need to address solid tumor treatments such as TIL and TCR in the near future. As the process and decisions on these issues take time, we plan to continue to engage with stakeholders to understand the needs necessary for patients and providers to get appropriate access as quickly as possible to these potentially lifesaving treatments. Our processes continue to evolve as innovative

treatments evolve.” ([58605 FR FY 2021 IPPS Final Rule](#))

- ***New mechanisms for rare diseases*** – FY 2023: “As discussed previously and in prior rulemaking, we generally prefer not to create a new MS–DRG unless it would include a substantial number of cases, as having large clinical cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights. We acknowledge the complexities related to classifying cases that are represented by low volumes in our claims data and believe that further review of this issue also aligns with our intent to consider how rare diseases or conditions may be classified under the IPPS....We will continue to explore appropriate mechanisms to address therapies indicated for rare diseases. We also refer the reader to section II.D.19.a of the preamble of this final rule for a discussion of the feedback received in response to the comment solicitation on possible mechanisms to address rare diseases and conditions in the MS–DRG structure.” ([48854 FR IPPS 2023 FR](#))
- ***Low volume MS-DRGs*** – FY 2023: “The MS–DRGs are a classification system intended to group together those diagnoses and procedures with similar clinical characteristics and utilization of resources. As discussed previously and in prior rulemaking, we generally prefer not to create a new MS–DRG unless it would include a substantial number of cases, as having large clinical cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights. We acknowledge the complexities related to classifying cases that are represented by low volumes in our claims data and believe that further review of this issue also aligns with our intent to consider how rare diseases or conditions may be classified under the IPPS.” (48854 FR IPPS 2023 FR)
- ***Engagement with stakeholders*** – FY 2023: “We noted in the proposed rule that in response to our statement in the FY 2022 IPPS/LTCH PPS final rule that we plan to continue engaging with interested parties on additional options for consideration in this field of cellular and gene therapies, we received additional feedback and suggestions, including recommendations for Town Hall meetings/listening sessions to discuss the interconnectedness of these issues; exploration of what was described as a different set and kind of MS–DRGs that would reward providers for controlling patient care costs, without consideration of product costs outside of their control; and evaluation of the creation and assignment of multiple MS–DRGs for cell and gene therapy cases: one to cover patient care costs, the other to cover product costs across therapeutic product categories. We stated we appreciated this additional feedback and will continue to consider these issues and suggestions in connection with future rulemaking. We also stated we intend to continue engaging with interested parties by sharing updates from our analysis of claims data as we examine and explore potential refinements for these therapies under the IPPS.” (FR 48806 FY IPPS 2023 Final Rule)

Given the multiple years that CMS has acknowledged the gravity of these issues, the ASTCT is disappointed that the agency has not publicly engaged stakeholders or made any proposals to address the known IPPS payment system issues for cell and gene therapies in the FY 2024 Proposed Rule.



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The agency acknowledged the critical importance of payment innovation through the release of the Centers for Medicare and Medicaid Innovation (CMMI) Cell and Gene Therapy Access model in February 2023. This model has the aim of “help[ing] Medicaid beneficiaries gain access to potentially life-changing, high-cost specialty drugs for illnesses like sickle cell disease and cancer.”⁸ In the Health and Human Services press release, CMS stated that: “Tackling the high costs of prescription drugs and increasing access to novel therapies continue to be priorities of the Biden-Harris Administration.” As described, the Cell and Gene Therapy Access Model will “help Medicaid beneficiaries gain access to potentially life-changing, high-cost specialty drugs for illnesses like sickle cell disease and cancer.” **ASTCT anxiously awaits details on the CMMI model as the therapies referenced by CMS in the announcement are not only vitally important to Medicaid beneficiaries, but many are exactly the same as those we seek to provide to Medicare beneficiaries. However, access has been and will continue to be constrained for Medicare beneficiaries without equivalent innovation within IPPS. This is particularly true for beneficiaries who are dual-eligible and, therefore, for whom Medicare coverage and payment is primary.**

The ASTCT acknowledges that CMS is being asked to do more than ever before, within a medical landscape that is increasingly complex, and with far fewer resources than the agency likely needs. Our member providers and hospitals are facing similar staff and resource constraints as they strive to provide innovative, potentially lifesaving and/or life-altering therapies to Medicare beneficiaries with hematologic malignancies or hematologic disorders. In the FY 2019 final rule, CMS noted that “it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that involves increased cost.”⁹ However, we note that it is equally inappropriate for CMS to expect hospitals to provide care at significant financial losses well beyond the IPPS averaging concept. **We ask CMS to prioritize these issues in FY 2024 to establish access to cell and gene therapies for beneficiaries who are in dire need.**

CMS Should Seek Stakeholder Input on New Payment Policies for Cell and Gene Therapies

Cell and gene therapies are changing the treatment landscape for numerous cancers and rare diseases in ways that are truly revolutionary. These therapies have also necessitated much change in the areas of coverage coding, and reimbursement and will continue to require further

⁸ Centers for Medicare & Medicaid Services (CMS), “Press Release: HHS Secretary Responds to the President’s Executive Order on Drug Prices,” Baltimore (MD): CMS, February 14, 2023:

<https://www.cms.gov/newsroom/press-releases/hhs-secretary-responds-presidents-executive-order-drug-prices>.

⁹ Centers for Medicare and Medicaid Services (CMS), “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims,” *Federal Register*, 2018; 83(160): 41144: <https://www.govinfo.gov/content/pkg/FR-2018-08-17/pdf/2018-16766.pdf> (FR 41201)



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improvements. **Therefore, the ASTCT reiterates that it is critical for CMS to hear firsthand from stakeholders, such as through the agency hosting a series of Town Hall meetings.**

This would not be unlike the series CMS held on the MS-DRG Complication and Comorbidity (CC)/Major Complication and Comorbidity (MCC) Comprehensive Analysis on October 8, 2019, and its Town Hall meetings held in 2021 on “Transitional Coverage for Emerging Technologies.”¹⁰

As noted, multiple cell and gene therapy approvals are anticipated during FY 2024 and a pattern of frequent approvals will likely continue over the next several years. Therefore, the ASTCT believes that now is the time for CMS to identify and advance solutions to ensure access for Medicare beneficiaries.

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

The ASTCT continues to appreciate the exceptional changes CMS has made to its payment and rate-setting methodologies for MS-DRG 018 (Chimeric Antigen Receptor T-cell and Other Immunotherapies) in recognition of the unique circumstances associated with CAR-T and similar therapies. The ASTCT continues to invest significant time and resources in educating its members on CMS’ coverage, coding, billing, and reimbursement provisions, including the development of a [CAR-T Coding & Billing Guide](#) to highlight and consolidate CMS’ instructions for hospitals.¹¹ Our members rely on this resource along with the webinars we provide to help explain CMS’ complex reimbursement and rate-setting systems.

Our members are involved in many of the pivotal trials for cell and gene therapies expected to be commercially available in the next several years. As a result, the ASTCT continues to study the MS-DRG classification and IPPS system’s ability to effectively classify and pay for these novel therapies.

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

ASTCT physician members are responsible for providing the clinical care associated with CAR-T therapy and other immunotherapies, which map to MS-DRG 018. Our review of the claims data revealed similar findings to what CMS reported in the rule: that provider charging practices are improving, as evidenced by a very small proportion of claims with standardized pharmacy charges less than \$373,000, along with the increase in the relative weight that we see for FY 2024.

¹⁰ Centers for Medicare & Medicaid Services (CMS), *Transcript: Transitional Coverage for Emerging Technologies Listening Session*, March 31, 2022: <https://www.cms.gov/files/document/transcripttransitionalcoverageofemergingtechnologylisteningsession03312022.pdf>.

¹¹ ASTCT, *CAR-T Coding & Billing Guide*, Chicago (IL): ASTCT, no date: <https://www.astct.org/advocate/car-t-coding-and-billing-guide>.



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Our understanding is that CMS proposes to eliminate this portion of its unique rate-setting methodology due to the marked improvement in providers reporting clinical trial cases with diagnosis code Z00.6. While the ASTCT is pleased to see that hospital billing practices have improved, we believe it is premature to eliminate the \$373,000 minimum standardized pharmacy charge as a filter to determine whether the CAR-T claim should be utilized for rate-setting. As the number of CAR-T treatment sites expands, hospitals that are new to CAR-T have to acclimate to the coding, billing, and mark-up rules. **The ASTCT requests that CMS keep both parts of its unique rate-setting methodology in place for at least one more fiscal year, so we can continue to monitor the claims data and its impact on the relative weight.**

Mitigate Charge Compression for MS-DRG 018 Cases

The ASTCT acknowledges that MS-DRG 018 has the highest relative weight in the IPPS system. The ASTCT also continues to note that the primary driver of the high costs associated with CAR-T is the CAR-T product acquisition cost, which CMS' rate-setting methodology, even with clinical trial cases set aside, does not fully account for appropriately in rate-setting. This underpayment trend continues year-over-year, despite providers heeding CMS' guidance that nothing precludes them from setting their charges in accordance with their cost-to-charge ratios (CCRs).

Despite the unique payment and rate-setting practices CMS has implemented for MS-DRG 018, our analysis of the proposed rule data files **indicates that 61% of MS-DRG 018 claims received substantial outlier payment.** The average outlier payment was just over \$111,000, which is nearly 27% of the total payment received by hospitals for those cases. It is critically important to note that the outlier payment for these claims were during a fiscal year when NTAPs were available for several products; meaning that the proportion of claims receiving outlier payment would have been even higher if NTAP was not available. For context, the proportion of claims receiving outlier dollars in MS-DRG 018 exceeds the next-highest outlier proportion MS-DRG by 20% (e.g., MS-DRG 001, Heart Transplant with MCC), with 41% of claims receiving outlier payment of an average of \$106,000, comprising 20% of total hospital case payment.

MS-DRG 018 showcases the known problem of charge compression, which CMS has tried to address from time to time. CMS' rate-setting methodology of applying the extremely low drug CCR to the pharmacy charges reported on MS-DRG 018 claims significantly underestimates the CAR-T product cost. ASTCT believes that the high proportion of MS-DRG 018 cases receiving outlier payment demonstrates that CMS has failed to achieve resource homogeneity for this MS-DRG and, therefore, threatens a key tenet of the IPPS.

As more hospitals appropriately improve their charging practices and in fiscal years where products no longer have NTAP, the percentage of cases receiving a substantial amount of their payment from outlier dollars will grow significantly, since the base payment of MS-DRG 018 is not reflective of the average cost of the case. Additionally, hospitals in low wage index areas will have a greater reliance on outlier dollars and draw even further on the pool.



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Even with the outlier payment, the reality is that most CAR-T cases are still underpaid. Based on CMS’ released data, the average payment across CAR-T cases was \$423,124. Many CAR-T cases still involve long and complex inpatient stays—the geometric and arithmetic mean lengths of stay are 13.0 and 15.2 days, respectively.¹² The two most recent CAR-T approvals were introduced at wholesale acquisition costs of \$465,000 and \$419,500, with no discounts available for inpatient use.¹³

The current CY 2023 Hospital Outpatient Prospective Payment System (OPPS) payment rates for the current FDA-approved CAR-T products are listed in the following table for reference.

HCPCS Code	Short Descriptor	SI	APC	CY 2023 Payment Rate
Q2054	Lisocabtagene car pos t	G	9413	\$434,918.00
Q2041	Axicabtagene ciloleucel car+	K	9035	\$422,884.77
Q2042	Tisagenlecleucel car pos t	K	9194	\$453,856.60
Q2053	Brexucabtagene car pos t	G	9391	\$422,940.00
Q2055	Idecabtagene vicleucel	G	9422	\$444,670.00
Q2056	Ciltacabtagene autoleucel	G	9498	\$478,950.00

CMS continues to pay for these products in the outpatient setting via its standard drug payment policy of Average Sales Price (ASP) +6%. Yet, the *total* IPPS average payment for a CAR-T case is barely equivalent to—or for some products, significantly below—the cost just for acquiring the drug. This means patient care costs for an average two weeks of inpatient care and any treatments for therapy-related toxicities is not paid via the MS-DRG. 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.”¹⁴ The ASTCT fears 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 in similar ways to how 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 a primary source of payment for the majority of cases within a

¹² Centers for Medicare and Medicaid Services (CMS), *FY2024 IPPS Proposed Rule Home Page (Table 5)*, Baltimore (MD): CMS, May 8, 2023: <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2024-ipp-pps-proposed-rule-home-page>.

¹³ Lui A, “Johnson & Johnson, Legend’s CAR-T Carvykti enters myeloma ring with FDA nod,” *FIERCE Pharma*, February 28, 2022: <https://www.fiercepharma.com/pharma/johnson-johnson-legend-car-t-cilta-cel-myeloma-ring-fda-approval-rivaling-bristol-myers>.

¹⁴ 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/>.



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single MS-DRG. By design, a hospital receiving outlier payment has already incurred a financial loss on that case (i.e., by absorbing the fixed loss threshold of more than \$40,000 and by receiving only 80% of the balance beyond that threshold) and losses of this magnitude cannot be made up with thin margins on other cases.

Almost two-thirds of CAR-T cases resulted in a loss, which raises a fundamental question about the adequacy of the base payment of MS-DRG 018. It also means that CAR-T is likely to be disproportionately drawing from the outlier pool and inflating the fixed loss threshold in a manner that affects all other MS-DRGs in the IPPS.

Therefore, the ASTCT requests that CMS utilize the “other” CCR to reduce CAR-T product charges (i.e. revenue code 0891) to cost starting in FY 2024 as a strategy to address charge compression. We further recommend that the “other” CCR remain in place until such time CMS proposes an alternative payment solution.

The use of the “other” CCR in place of the currently applied national drug CCR would allow CMS to immediately mitigate the significant charge compression problem and would result in a more appropriate case cost and a higher relative weight for MS-DRG 018. A higher base payment will instantly reduce the proportion of cases receiving outlier payment, as well as the absolute amount of outlier dollars paid for MS-DRG 018 cases. This will aid in bringing MS-DRG 018’s proportion of outlier payment more in line with other MS-DRGs. CMS should use the “other” CCR until it has been able to collect data via cost center 0078, which was recently made effective starting with fiscal years ending on and after 10/1/2022.

While this may appear to be another unique methodological modification that is implemented only for MS-DRG 018, we believe it is a logical step for several reasons. First, the National Uniform Billing Committee (NUBC) created dedicated revenue codes (087x and 089x) specifically for cell and gene therapies in recognition that the products are a unique class of drugs/biologics requiring claim reporting beyond the existing pharmacy revenue codes 25x and 63x. Additionally, CMS created line 0078 and has instructed providers to reclassify cell therapy product costs in recognition of the fact that these costs are unique and should be segregated. We believe the creation of unique revenue codes and the unique cost center line in the cost report will enable CMS to utilize this information in the future to possibly create and use a 20th cost center to use in rate-setting.

Second, CMS has not released new ideas or methodologies based on comments submitted by numerous stakeholders, including the ASTCT—despite CMS’ request for comment on payment methodologies for rare disease and novel therapies in the FY 2023 IPPS Proposed Rule. The ASTCT’s proposed solution works within the bounds of CMS’ current rate-setting system and presents a solution that would result in a more appropriate payment for MS-DRG 018.

Third, CAR-T is the first of many cell and gene therapies for which hospitals will face the same challenge: providing care to beneficiaries at a significant loss while disproportionately pulling dollars from the outlier pool. By addressing this significant charge compression now, CMS will



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provide immediate financial relief to providers while gaining time to study new ideas for how to pay for these novel therapies and while allowing data to develop in cost center 0078. (*Note: CMS has not yet instructed providers to report their gene therapy costs to line 0078, despite ASTCT having requested this previously*).

Last, ASTCT’s members appreciated CMS’ provision of a table in the FY 2023 Proposed Rule¹⁵ that displayed each PCS code mapped to MS-DRG 018, along with the number of cases, the Average Length of Stay, Average Costs, and the number of codes with Z00.6 (indicating a clinical trial). **The ASTCT requests that CMS continue to provide this type of summary information on cases within MS-DRG 018, as it is very helpful to stakeholders that are unable to perform their own detailed data analyses.**

MS-DRG 014: Allogeneic Bone Marrow (Stem Cell) Transplantation Section 108 Implementation

In December 2019, Congress created a cost-based reimbursement mandate for donor search and cell acquisition costs for allogeneic hematopoietic stem cell transplant (alloHSCT) in Section 108 of the Further Consolidated Appropriations Act of 2020 (Section 108). Section 108 provides a solution to the long-standing issue of inadequate reimbursement for alloHSCT under IPPS, with the goal of improving access to alloHSCT for Medicare beneficiaries with otherwise fatal hematologic malignancies. Section 108 identifies the various types of donor sources that may be utilized as part of an alloHSCT, specifically including bone marrow, peripheral blood stem cells, and hematopoietic stem cells derived from umbilical cord blood. CMS formally implemented Section 108 in FY 2021 and released additional detailed cost reporting instructions in December 2022.

ASTCT wishes to note several items related to the implementation of Section 108 for CMS’ consideration:

Address NTAP-related revenue integrity concerns about donor sources

The NTAP application for a novel donor source—omidubicel—has introduced the potential for a revenue integrity issue related to Section 108 and MS-DRG 014. Omidubicel is an example of a type of donor source that may be utilized by ASTCT members to treat Medicare beneficiaries with hematologic malignancies. Omidubicel is not the first FDA-approved donor source, as all cord blood units utilized for alloHSCT are regulated by the FDA.¹⁶ Omidubicel is used in the same manner as traditionally acquired donor sources in the allogeneic hematopoietic stem cell

¹⁵ Centers for Medicare and Medicaid Services (CMS), [“FY 2023 Inpatient Prospective Payment System \(IPPS\) Proposed Rule,”](#) *Federal Register*, 2022; 87(90): 28131.

¹⁶ Food and Drug Administration (FDA), *Approved Cellular and Gene Therapy Products*, Rockville (MD): FDA Office of Tissues and Advanced Therapies, February 19, 2023: <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>.



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transplant process. As such, the ASTCT believes that CMS should treat it as equivalent to all other donor sources for the purpose of alloHSCT coding, billing, and reimbursement.

As of FY 2021, CMS excludes donor search and cell acquisition costs from both the current year claim payment calculation and from future rate-setting for MS-DRG 014 (Allogeneic Bone Marrow Transplant) as part of Section 108 implementation. CMS must remove the donor search and cell acquisition charges and costs to avoid double-paying for these through the MS-DRG and through the cost report at time of settlement. Per statute, this unique mechanism applies to all donor sources, even novel ones. Novel donor sources are not appropriate to incorporate into the MS-DRG system through NTAP, since their costs are separately paid through the cost report. The ASTCT understands the purpose of NTAP is to incorporate the costs of a new technology or service into the future base MS-DRG payment rate. In the case of allogeneic hematopoietic stem cell donor sources, however, CMS does not need to do that, since it has already implemented a separate mechanism to recognize the costs of donor sources for payment.

CMS has issued cost report instructions that require providers to report all actual charges for donor search, which includes services for working up related donors, as well as searching for and finding the final unrelated donor, and reporting all of these actual charges along with the charge for the donor cells ultimately selected for the stem cell transplant. With an omidubicel hematopoietic stem cell transplant, providers will typically have charges for a related donor search and Human Leukocyte Antigen (HLA) typing, along with unrelated donor search charges. If omidubicel is ultimately selected as a donor source for the alloHSCT, then all of these charges will be added together and reported on the transplant recipient's claim under revenue code 0815.

If CMS approves omidubicel for NTAP and clearly explains in the final rule why omidubicel is not eligible for Section 108 reimbursement (per the definition of allogeneic hematopoietic stem cell transplant as defined in 42 CFR 412.113e), then the agency must then resolve multiple complex short- and long-term issues:

- Hospitals consider omidubicel to be an allogeneic hematopoietic stem cell transplant donor source and, as a consequence, will report it pursuant to HIPAA transaction sets under revenue code 0815. CMS excludes charges reported in 0815 for MS-DRG payment and rate-setting. This will exclude omidubicel cost from the claim and hospitals will not receive any intended NTAP, or any outlier payment, unless CMS obtains NUBC approval to create additional logic or instruct hospitals to report charges differently.
- If hospitals report omidubicel with non-stem cell revenue codes (such as 250, 636, or 891), per CMS' instruction, they will potentially receive NTAP and outlier payment, and this line-item information from the claim will also be utilized for MS-DRG 014 rate-setting. This will inflate the relative weight and base payment for MS-DRG 014 in a way that counters CMS' removal of donor cell costs.
- Hospitals will need specific instructions from CMS on which donor costs to report via revenue code 0815 versus reporting the omidubicel cost, as these cases will continue to have costs associated with the process of identifying an allogeneic hematopoietic stem



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cell donor, such as HLA typing of genetic relatives and unrelated potential donors, as well as the cell acquisition cost.

The ASTCT requests that CMS respect Congress’ intention for increased Medicare beneficiary access to alloHSCT through donor search and cell acquisition cost-based reimbursement by ensuring cost-based payment for all allogeneic hematopoietic stem cell donor sources, including novel donor sources like omidubicel.

Update Medicare Advantage Payment Methodologies

Medicare Advantage (MA) plans that rely on CMS’ MS-DRG methodology have been inconsistent in recognizing separate cost-based payment for donor search cell and acquisition costs pursuant to Section 108. **The ASTCT requests that CMS instruct MA plans to make cost-based payment for donor search and cell acquisition costs for allogeneic hematopoietic stem cell transplants as of the effective date of Section 108.** The ASTCT continues to hear from hospitals that some MA plans do not understand the rate-setting implications of Section 108 and have not modified their payment policies to account for the decrease in the MS-DRG 014 relative weight that resulted from the removal of these costs.

As has been requested in prior years by the National Marrow Donor Program/Be The Match (NMDP), the ASTCT is also requesting CMS to update its *Out-of-Network Medicare Advantage Guide* instructions to MA plans for out-of-network cases.¹⁷ CMS should update these instructions to include donor search and cell acquisition costs for alloHSCT as part of the instruction that MA plans are required to pay the full Medicare allowed cost for an organ acquisition. CMS also should update the applicable MA manual sections and guidance materials that refer to alloHSCT to include donor search and cell acquisition costs.

Allow more time for cost-reporting amendments related to Section 108

There was 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 in calendar year 2022, and cost reporting software updates were not finalized until early-2023. Hence, transplant centers have had limited time to gather cost and revenue data to accurately complete these forms. **The ASTCT requests that CMS allow transplant centers at least 90 days to file and permit them to amend each cost report that was impacted by the delayed cost reporting instructions.**

¹⁷ Centers for Medicare & Medicaid Services, *MA Payment Guide for Out of Network Payments: 4/15/2015 Update*, Baltimore (MD): CMS, 2015: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/downloads/oonpayments.pdf>.

Implement a Medicare Code Editor edit for revenue code 0815

In the proposed rule, CMS asked for comments on what types of edits should be included in the Medicare Code Editor (MCE). The ASTCT requests that CMS implement an edit for claims with allogeneic ICD-10-PCS codes that group to MS-DRG 014, such that it will be rejected 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 help ensure accurate claims reporting to CMS by transplant centers, ensure the accuracy of its budget neutrality calculation and also help 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. **Out of concern for program integrity, and as part of our efforts to improve the accurate billing of alloHSCT and future rate-setting for MS-DRG 014, the ASTCT asks CMS to implement this MCE edit with the release of the FY 2024 IPPS final rule.**

MS-DRG 016 & 017: Autologous Bone Marrow Transplant with and without CC/MCC

Assignment of HSC Gene Therapies to MS-DRGs 016 and 017

CMS has assigned multiple new procedure codes to represent transplants that are performed utilizing an autologous graft that has been genetically modified *ex vivo* to MS-DRGs 016 and 017. The ASTCT agrees that this mapping—and the proposed mapping of procedure codes XW133H9, XW133J8, XW143H9 and XW142J8 in FY 2024 to these same MS-DRGs—is clinically appropriate.

Payment Policies for HSC Gene Therapies Assigned to MS-DRGs 016 and 017

In addition to “traditional” autologous stem cell transplant, MS-DRGs 016 and 017 now include the following PCS codes, representing multiple HSC gene therapies:

ICD-10-PCS Code	Code Description
XW133B8	Transfusion of Betibeglogene Autotemcel into Peripheral Vein, Percutaneous Approach, New Technology Group 8
XW143B8	Transfusion of Betibeglogene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 8
XW133F8	Transfusion of OTL-103 into Peripheral Vein, Percutaneous Approach, New Technology Group 8



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XW143F8	Transfusion of OTL-103 into Central Vein, Percutaneous Approach, New Technology Group 8
XW133G8	Transfusion of OTL-200 into Peripheral Vein, Percutaneous Approach, New Technology Group 8
XW143G8	Transfusion of OTL-200 into Central Vein, Percutaneous Approach, New Technology Group 8
XW133H9	Transfusion of Lovotibeglogene Autotemcel into Peripheral Vein, Percutaneous Approach, New Technology Group 9
XW133J8	Transfusion of Exagamglogene Autotemcel into Peripheral Vein, Percutaneous Approach, New Technology Group 8
XW143H9	Transfusion of Lovotibeglogene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 9
XW143J8	Transfusion of Exagamglogene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 8

While the assignment of the listed procedure codes to MS-DRGs 016 and 017 is clinically appropriate, the resource use associated with these therapies will far exceed what is currently represented by the relative weight for these MS-DRGs. Of the products represented by these codes, only one (betibeglogene autotemcel) is currently approved by the FDA for marketing in the United States,¹⁸ although several more may be approved by the end of FY 2024.

Betibeglogene autotemcel is indicated for the treatment of transfusion-dependent beta-thalassemia and has a list price of \$2.8M.¹⁹ The prices of other therapies are unknown in advance of FDA approval. The ASTCT recognizes that it is important to assess the overall clinical and economic value of very high-cost therapies and is ready to engage in such discussions with CMS, when needed.

As is the case with CAR-T, hospitals do not have a mechanism to pass the acquisition costs of these therapies directly to CMS; therefore, they must purchase the therapy, administer it to a Medicare beneficiary, bill CMS, and be paid through the IPPS. At a proposed national unadjusted payment rate of \$43,292, MS-DRGs 016 and 017 will be woefully inadequate to compensate hospitals for the use of these technologies at the current and expected prices, even with NTAP in place and the application of hospital adjusters. There is no combination of MS-DRG or NTAP payment amount within IPPS—even MS-DRG 018—that would result in an appropriate payment for these types of therapies.

In the scenarios the ASTCT has modeled, the potential losses could be in the hundreds of thousands of dollars, *even when only compared to the drug acquisition cost and before including the costs of a multi-week hospital stay to allow for post-transplant engraftment.* If CMS does not

¹⁸ Food and Drug Administration (FDA), *Vaccines, Blood & Biologics: ZYNTEGLO*, Rockville (MD): FDA, September 19, 2022: <https://www.fda.gov/vaccines-blood-biologics/zynteglo>.

¹⁹ Bluebird bio, *Company Presentation*, May 2023: <https://investor.bluebirdbio.com/static-files/e9879aae-8413-498b-8c67-3a558b4abe61>.

address this issue with urgency, the inadequate payment rates will severely hinder the ability of Medicare beneficiaries to access forthcoming gene therapies for sickle cell disease.

There are also technical claims issues that need to be addressed, as was flagged by stakeholders at the April 2023 NUBC meeting. The paper UB-04 claims cannot contain more than 9 digits in the charge field. This issue could result in a hospital being unable to report appropriate charges for these gene therapies. For example, it would be reasonable and necessary for a hospital with an overall CCR of .25 to report a dollar charge of at least \$11,200,000 for a product with a cost of \$2.8M if it heeds CMS' guidance and sets its charge in accordance with its CCR (i.e. \$2.8M divided by 0.25 = \$11,200,000). However, the existing paper claim form will not accept this charge.

While CMMI's proposed Cell and Gene Therapy Access Model focuses on HSC gene therapies, and sickle cell disease in particular, the model (as proposed) will not aid the substantial number of affected dual-eligible individuals whose care is paid for by IPPS.²⁰

As CMS knows dual-eligible individuals are both Medicaid and Medicare beneficiaries, with Medicare being primary. Therefore, these individuals are subject to the coverage and payment policies that govern all other fee-for-service (FFS) Medicare beneficiaries. As stated in this letter's preamble, CMS has alluded to multiple potential changes to the IPPS system for rare diseases, yet the agency has not put anything forward to address these issues in the FY 2024 proposed rule.

Access to HSC gene therapies for sickle cell disease is a health equity issue and the ASTCT requests that CMS treat it as such with innovative payment solutions for both Medicaid and Medicare beneficiaries. This aligns with the broader priorities of HHS—the U.S. Office of Disease Prevention and Health Promotion has specifically called on CMS to increase the proportion of Medicare beneficiaries with sickle cell disease who received disease-modifying therapies.²¹ CMS' many references to health equity within the proposed rule are almost entirely focused on the quality reporting data elements. While important, those neither acknowledge nor address the health equity issues being exacerbated by the inadequate payment structure of the IPPS.

The ASTCT requests that CMS begin planning now for the one or more of the following: 1) establishment of a new MS-DRG for autologous *ex vivo* HSC gene therapies for the FY 2025 cycle, 2) proposal of a new payment mechanism for acquisition of the HSC gene

²⁰ Wilson-Frederick SM, Hulihan M, Blaz J, et al., *Prevalence of Sickle Cell Disease among Medicare Fee-for-Service Beneficiaries (Data Highlight, No. 15)*, Baltimore (MD): CMS Office of Minority Health, 2019: <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-15-Sickle-Cell-Disease.pdf>.

²¹ US Department of Health and Human Services (HHS), *Healthy People 2030, BDDBS 02: Increase the proportion of people with sickle cell disease on Medicare who received disease-modifying therapies*, Washington (DC): HHS, no date: <https://health.gov/healthypeople/objectives-and-data/browse-objectives/blood-disorders/increase-proportion-people-sickle-cell-disease-medicare-who-received-disease-modifying-therapies-bdbs-02/data-methodology>.



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therapy products, or 3) exploration of the inclusion of Medicare beneficiaries in innovative payment models being put forward by CMMI.

General IPPS Provisions

New Technology Add-On Payments

Summary of proposed changes to NTAP process and timelines

CMS' proposed changes for the FY 2025 NTAP cycle are the following:

- 1) Requiring all (not-yet FDA-approved) applicants to demonstrate that they have a complete and active FDA market authorization request via documentation of FDA filing or FDA acceptance of filing; and
- 2) Requiring all applicants to receive FDA market authorization by May 1 of the year prior to the fiscal year for which they have applied, rather than the July 1 deadline that is currently in place.

CMS states that these proposals will “*significantly improve [CMS’] ability to evaluate whether a technology is eligible for new technology add-on payment.*” (p. 582.) CMS also states that “[u]ltimately, it is difficult for CMS to review and for interested parties to comment on a product that has not yet been submitted to FDA, as multiple sections of the new technology add-on payment applications lack preliminary information that is more likely to be available after an FDA submission. Public input is an important part of our assessment of whether a technology meets the new technology add-on payment criteria, particularly as technology becomes more complex and specialized.” (p. 583.)

ASTCT members and their affiliated hospitals are greatly impacted by NTAP processes, timelines, and reimbursement. They are frequently the only specialists to provide novel immune effector cell therapies like CAR-T, hematopoietic stem cell gene therapies, and new medications associated with the provision of stem cell transplantation. This expertise guides the ASTCT in making the following comments on CMS’ NTAP proposals.

High volumes of NTAP applications will be commonplace going forward

All pipeline estimates of medical innovation point to only increasing volume of new technologies entering the U.S. market for the foreseeable future.^{22, 23, 24} Said another way, the

²² CVS Health, *Gene Therapy Pipeline Q3 2022 -1Q 2027: Projected Treatments and Approval Timelines*, CVS Health, 2022: <https://payorsolutions.cvshealth.com/sites/default/files/q3-2022-gene-therapy-treatments-approval-timelines.pdf>.

²³ Alliance for Regenerative Medicine, *The Sector Snapshot: April 2023*, Washington (DC): Alliance for Regenerative Medicine, 2023: <https://alliancerm.org/sector-snapshot/>.

²⁴ MIT NEWDIGS, “Updated projection of US durable cell and gene therapies product-indication approvals based on December 2019 development pipeline,” *MIT NEWDIGS Research Brief 2020F207-v051 Pipeline Analysis*,



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number of NTAP applicants will only continue to increase. By nature, all of these technologies will be scientifically complex for CMS to evaluate. The ASTCT empathizes with the combination of increasing volume and increasing complexity faced by CMS. *However, the proposals that CMS made has presented will instead further delay the availability of NTAP dollars to hospitals that want to provide the best available care for Medicare beneficiaries.*

To adequately address this situation, we urge CMS to consider alternative solutions than the ones being proposed in this rule. We recommend that CMS adopt a process of conditional approvals and multiple approval timeframes per year. Doing so will meet the Congressional intent behind NTAP, rather than continuing to artificially winnow a robust field of applicants down to a group small enough to fit within the confines and resources of the current rule-making cycle. At a minimum, CMS could approve NTAP consistent with the current ICD-10 update cycle of October 1 and April 1 each year. **We encourage CMS to seek comment and stakeholder support for the resources it needs to align the NTAP process with the current speed of medical innovation.**

CMS also refers to a substantial increase in volume of applications both from the program’s inception and during the last several fiscal years, citing a 200% increase in applications between FY 2020 and FY 2024. In addition to these new applications, CMS must also manage several dozen technologies that currently have NTAP status and must be reviewed for proposed continuation or discontinuation in any given fiscal year’s rule-making cycle. The time and effort CMS dedicates to the various aspects of NTAP is reflected in the more than 300 pages of text associated with NTAP in the FY 2024 proposed rule alone.

The NTAP program was established for “expeditiously incorporating new medical services and technologies” into the IPPS system for purposes of “ensuring appropriate payments” to hospitals utilizing these services and technologies to care for Medicare beneficiaries.²⁵ The ASTCT understands the staff and resource constraints within the agency’s rule-making team. Nonetheless, the increased volume of NTAP applications is not temporary; it requires CMS to consider new approaches to the NTAP annual cycle, including processing and vetting applications more than once per calendar year. **CMS could consider making each NTAP approval valid for the duration of the eligible time, without requiring re-approval during each IPPS cycle.**

Proposal to require FDA approval by May 1

In reference to the proposal to shift the FDA approval or clearance deadline from July 1 to May 1, CMS states that it believes “*the July 1 deadline may no longer provide sufficient time to fully evaluate the new technology applications in advance of the issuance of the final rule, including information that does not become available until FDA approval or clearance. The technologies that are the subject of new technology add-on payment applications are increasingly complex,*

Cambridge (MA): NEWDIGS, 2020: <https://newdigs.tuftsmedicalcenter.org/updated-projection-of-us-durable-cell-and-gene-therapies-product-indication-approvals-based-on-december-2019-development-pipeline/>.

²⁵ H.R. 4577 of the 106th Congress: <https://www.congress.gov/106/plaws/publ554/PLAW-106publ554.pdf>.



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such as fourth- and fifth-line therapies and devices utilizing artificial intelligence algorithms.”
(70 FY 47362)

CMS’ proposal to modify the FDA approval date requirement from July 1 to May 1 will mean that very few NTAP applicants will receive a third year of NTAP status.

CMS states that: “Our policy is that a medical service or technology may continue to be considered ‘new’ for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product’s entry onto the U.S. market occurs in the latter half of the fiscal year.” (70 FR 47362)

The latter half of the fiscal year translates to April 1–October 1. Under CMS’ current policy, if the cut-off for new technologies to receive consideration for NTAP is moved to May 1, only technologies that are approved between April 1–April 30 during their initial newness year will have the potential for an extension of a third year of NTAP. For low-volume technologies, especially autologous cell and gene therapies that need longer time frames for claims data to accumulate, a third year of NTAP status may be critical to ensure enough claims data accumulate into the IPPS to impact relative weights and/or drive the development of a new (or split) MS-DRG. **ASTCT asks that CMS approve NTAP applications no less than twice per year, instead of adjusting the current timeline, to allow for more time between applicant approval and the release of the rule materials.**

CMS’ proposal to require a complete FDA filing and/or notification of FDA filing acceptance is unlikely to result in a significant decrease to the total number of annual applicants, including those that apply a cycle in advance of a realistic FDA approval timeline. An applicant that completes filing in the months immediately preceding the NTAP deadline of mid-October may not receive the anticipated FDA approval until after May 1, even with Priority Review status; products that are subject to the traditional review timeline may not receive approval until late Fall. Applicants will likely continue to pursue an NTAP application as a “just in case” strategy, or to solicit information on what concerns CMS may have with a future application, even if they are unlikely to receive FDA approval until well after the proposed May 1 deadline.

More importantly to ASTCT members, a shift to May 1 further delays the availability of NTAP payments for new technologies and services that would otherwise be eligible. With the current set of timelines, applicants that receive approval shortly after the July 1 deadline need to reapply for the following fiscal year, creating a delay between FDA approval and availability of NTAP dollars of up to 15 months. **The proposed May 1 FDA approval deadline extends this already problematic timeframe by two months—creating a situation in which qualified**



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technologies may not have NTAP dollars available for up to 17 months post-approval. This stands in stark contrast to the OPPS' process, which awards pass-through status to qualifying drugs or technologies on a rolling basis and within months of approval. Making it *more difficult* for applicants to receive NTAP status for the fiscal year immediately following their FDA approval does not match the intent of the NTAP legislation.

Products that qualify for NTAP are, by definition, those for which costs are not accounted for within the current DRG payment rates. Providers do not have any ability to impact the prices for obtaining these new technologies and are required to utilize a buy-and-bill pathway for acquisition on behalf of Medicare beneficiaries. When there is a long period between the FDA's marketing authorization and NTAP availability, hospitals are faced with only two bad options. They can either provide the product without the additional NTAP dollars (i.e., at a substantial loss) or provide beneficiaries with alternative care options that may not have the same clinical benefit as the new therapy. Neither of these options serves Medicare beneficiaries in a way that matches the Congressional intent for the legislation behind NTAP. Finally, the lack of availability of NTAP dollars for an extended timeframe means that hospitals that do utilize these new technologies will draw from the outlier pool for far longer than would otherwise be necessary.

Alternative Pathway for Cell and Gene Therapies

The ASTCT asks that CMS consider an alternative NTAP pathway for cell and gene therapies utilized in the IPPS similar to the pathway implemented for Qualified Infectious Disease Products (QIDPs) in FY 2020, for the following reasons:

- Cell and gene therapies are generally priced at levels where only recovering up to 65% of the acquisition cost translates into extreme dollar losses for providers (e.g. losses of \$162,000 for a \$465,000 product or \$980,000 for a \$2.8M product);
- Very few hospitals in the United States are qualified to provide cell and gene therapies, which further concentrates the potential losses;
- Most of the currently available products are created uniquely for specific individuals and have lower volumes than many other drugs that receive NTAP.

An alternative pathway that allows for increased cost recovery would substantially assist with the establishment of cell and gene therapies in the Medicare beneficiary population. **The ASTCT asks CMS to consider and seek comments on an alternative NTAP pathway for cell and gene therapies.**

Newness Start Date for Cell and Gene Therapies

Proposed discontinuation of Idecabtagene vicleucel and Ciltacabtagene autoluecel

The ASTCT does not typically comment on individual NTAP applications. Nonetheless, we wish to comment on the proposed discontinuation of NTAP status for two CAR-T products, as this is emblematic of a policy issue relating to cell and gene therapies. CMS has stated in multiple



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NTAP product discussions that it generally defines the newness start date as the date when the product became commercially available—i.e., the FDA approval date. The ASTCT disagrees that this standard should be applied to cell and gene therapies.

CMS proposes to discontinue NTAP status for both idecabtagene (ide-cel) and ciltacabtagene autoleucel (cilta-cel) due to the 3-year anniversary of newness date associated with ide-cel. In the rule, CMS states that *“Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product’s entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).”*

In the case of ide-cel and cilta-cel, the 3-year anniversary of the newness date associated with both products (due to being declared substantially similar) is March 26, 2024. This is four calendar days prior to the second half of the fiscal year, when the products would be eligible for a third year of NTAP status. The ASTCT does not have access to sales or ordering information from these products. However, all currently approved CAR-T products, including ide-cel and cilta-cel, are autologous products—meaning they are manufactured from a patients’ own cells for future reinfusion to the patient whose disease is being treated. These products are not available as off-the-shelf therapies and take weeks to manufacture, including apheresis, gene-editing of cells and quality testing. Due to these processes, in conjunction with certifying treatment sites on the FDA-required REMS procedures, the first commercial shipment of ide-cel likely took place weeks after FDA approval of March 26, 2021 and would have crossed the April 1 threshold date to be within the second half of the fiscal year.

In a Medicaid proposed rule issued by CMS in May 2023, CMS proposed to determine the “market date” (i.e., newness start date) for Medicaid Covered Outpatient Drugs (COD) as *“the earliest date on which the drug was first sold, by any manufacturer” and for first sold to be defined as “any sale of the COD.” (FR 88 34257)* This type of definition seems far more logical for cell and gene therapies due to their unique manufacturing parameters and should be considered as a viable option for the Medicare NTAP program.

The ASTCT requests that CMS consider a standard third-year extension of NTAP for cell and gene therapies, due to the unique manufacturing process and low volume nature of the diseases treated. Additionally, the ASTCT requests that CMS extend NTAP into FY 2024 for both ide-cel and cilta-cel, as the newness start date being utilized is extremely close to the mid-year benchmark and also likely to be functionally inaccurate.

NTAP Application for omidubicel

While ASTCT does not typically comment on individual NTAP applications, the application for omidubicel raises several structural reimbursement concerns associated with MS-DRG 014. NTAP is an important IPPS payment program to recognize and incorporate the costs of new



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medical services and technologies into the MS-DRG system. However, the ASTCT believes that NTAP is duplicative in the case of allogeneic stem cell donor sources and is not necessary, since CMS has already established a cost-based reimbursement methodology via Section 108 for reimbursing donor sources. Please see our comments under the MS-DRG 014 section of this letter for additional details.

Growth in Medicare Advantage is Diminishing Claims Volume for Rate-setting

Based on recent data from CMS, more than 50% of Medicare beneficiaries are now enrolled in Medicare Advantage plans rather than traditional Part A and Part B.²⁶ The Congressional Budget Office has predicted that the percent of beneficiaries enrolled in MA plans will grow to more than 61% by 2032.²⁷

MA enrollment also 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 (Michigan, Minnesota and Wisconsin).²⁸ This variation means that the FFS claims that Medicare utilizes are not only decreasing in total number (representing less than half of beneficiaries) but also becoming increasingly 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 fewer) are also the states with the highest number of academic and specialized medical centers, where many patients with rare diseases seek specialized care.

As the percent of beneficiaries enrolled in FFS decreases, the number of FFS claims used for rate-setting will also decrease and become increasingly less representative for predicting resource utilization. **In the FY 2022 data being utilized for FY 2024 rate-setting, there were 390 MA CAR-T claims that were not included in rate-setting—an amount that would have increased the total volume by 50%.** 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, as CMS has acknowledged, MA plans utilize IPPS MS-DRG base payments to base their hospital payment for MA beneficiaries. For the reasons stated above, the use of a set of claims that is no longer nationally representative to establish payment for treating both FFS and MA beneficiaries is not logical.

²⁶ 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/>.

²⁷ 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/>.

²⁸ 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/>.



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Hospitals that bill an MA plan for an inpatient stay must also submit a copy of that claim to their local Medicare Administrative Contractor (MAC) for informational purposes, known as a “shadow claim.” **The 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 the analyses CMS conducts on claims more statistically robust and 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 provided to them by IPPS hospitals. Additionally, it is important that CMS re-examine the continued use of the 500-claim volume threshold used for determining MS-DRG splits given decreasing total pool of FFS claims.

The ASTCT asks that CMS conduct or commission a study from a reputable firm such as RAND or RTI that examines the effect of including shadow claims with FFS claims on: 1) rate-setting for rare diseases and procedures, such as the administration of CAR-T, and 2) volumes utilized for establishing new and/or splitting current MS-DRGs.

Questions about the MEARIS System

In the rule, CMS addressed several topics that require research and analysis; the agency stated that it will continue to consider those topics in future rulemaking and asked for comments from interested parties, saying comments and suggestions should be submitted for FY 2025 via MEARIS. CMS also noted that all MS-DRG classification change requests should be submitted via MEARIS by October 20, and that it was no longer receiving MS-DRG requests via email.

The ASTCT requests that CMS review the options within MEARIS to ensure that the system is able to accept generalized comments and/or comments impacting more than a single MS-DRG. Our experience is that MEARIS requires users to answer very specific questions that are applicable only when a requestor is asking for a new MS-DRG, a split, a name change, or reassignment of a procedure or diagnosis. CMS’s requests for comments from interested parties on broad topics will be problematic to submit given the current MEARIS structure.

In the past, the ASTCT has submitted MS-DRG-related requests and comments via email to CMS that were relevant to multiple MS-DRGs and/or did not fall squarely within the construct of the MEARIS fields and systems. **The ASTCT asks CMS to revise MEARIS such that more general comments on the IPPS or the MS-DRG classification system as a whole can be provided or to continue to allow email submissions of comments that are not MS-DRG specific.** An alternative would be for CMS to add a category that supports free text requests.

CC/MCC Criteria Applying to Existing MS-DRGs

In this rule, CMS again proposes to apply the CC/MCC criteria to existing MS-DRGs and to delay implementing the application until FY 2025. Unlike in prior rules, CMS published additional information on the impact of this change, including the release of an alternative



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group (v41.A), an alternative Table 5 with relative weights, an alternative Case Mix Index (CMI), and several tables with additional data. We appreciate the provision of this additional detail and insight.

The ASTCT supports CMS’ proposal to delay the implementation of the application of the criteria for another year. While the additional data provide further insight, we still are unsure why CMS is pursuing the application of this criteria to existing MS-DRGs. The information released also does not explain how these changes will improve the explanatory power of the MS-DRG system.

We are concerned that the 500-case volume threshold may be too high, particularly for low-volume services and MS-DRGs. This is particularly concerning considering MA’s tremendous growth and the subsequent decrease in the number of FFS claims flowing into rate-setting, as discussed above. We think this element of the criteria deserves further analysis, and request that CMS release further analysis about the benefits of this proposal. The ASTCT believes that the deletions, reweighting, and renumbering of the MS-DRGs will have significant impacts on the MS-DRG system. **The ASTCT requests that CMS further illuminate the rationale under which it is pursuing the application of these changes.**

The ASTCT sincerely appreciates CMS’ review of our comments and would be pleased to engage with CMS on any technical questions it may have.