

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

October 20, 2026

RE: New MS-DRG Request letter

Dear Administrator Oz:

The American Society for Transplantation and Cellular Therapy (ASTCT) is a professional membership association of more than 3,900 physicians, investigators, and other health care professionals. Our mission is to advance hematopoietic cell transplantation and cellular therapies through groundbreaking research, high-quality education, impactful advocacy, and clinical excellence.

ASTCT is submitting a request for a new MS-DRG for gene therapies via the MEARIS system and is summarizing key aspects of that request in this letter for reference. ASTCT has appreciated the dialogue between CMS and stakeholders within the IPPS rulemaking cycle that has occurred over the past several years, and the discussions about ways to address the payment issues currently affecting the provision of cell and gene therapies. ASTCT understands that these therapies are still very new, have costs beyond what IPPS payment structures were designed for, and that volumes of these therapies are far below the standard volume thresholds that CMS would typically require. However, given the life-altering and/or life-saving benefit many of these therapies afford, in combination with the expiration of NTAP for several of the therapies, ASTCT is moving forward with this request now to ensure that Medicare beneficiaries can access the care they need.

ASTCT has shared many ideas for adjustments to the MS-DRG payment system over the past several rulemaking cycles to provide CMS with new options to consider. Our current ask fits within CMS' standard MS-DRG rate-setting methodologies, and mirrors the payment and rate-setting adjustment associated with MS-DRG 018. As our data analysis section will show, current volumes are low. This is to be expected at this point in time due to a combination of recent FDA approval dates, lengthy care episodes, and limited (but still critically important) use in the Medicare beneficiary population. We ask that this comparatively low volume not dissuade CMS from action, however. Hospitals need a sustainable reimbursement solution to continue providing these innovative therapies to patients, particularly those products with NTAP status that will expire after FY 2027.

ASTCT understands that other stakeholders may be asking for different groupings or payment structures. We encourage CMS to put forward all request options in the FY 2028 IPPS proposed rule so that the community can evaluate them and provide CMS with the feedback that the agency needs in order to move forward.

ASTCT thanks CMS for the time and attention the agency continues to put toward integrating these innovative therapies into the IPPS. We stand ready to discuss any aspect of our request with your staff.

Regards,



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ASTCT President
2026-2027

Please send any correspondence to ASTCT Director of Government Relations, Molly Ford, at MFord@astct.org.

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Background Related to ASTCT's Request

The American Society for Transplantation and Cellular Therapy (ASTCT) requests that CMS create a new Pre-MDC MS-DRG, potentially entitled "Gene Therapies," for one-time *in vivo* and *ex vivo* gene therapies that treat debilitating or life-threatening illnesses caused by genetic mutations. The growing number of FDA approvals for these products includes autologous hematopoietic stem cell therapies for sickle cell disease, beta thalassemia, and other inherited blood and immune disorders, as well as therapies for hemophilia, neurologic disease, and severe skin disease. Although the diseases and delivery methods differ, all of these therapies are meant to make a long-lasting (and hopefully permanent) change to the patient's genetic code in service of modifying their disease course. These therapies also require specialized clinical teams for patient evaluation and administration, with advanced logistics, containment and engineering controls, special handling, and post-administration precautions. In clinical expertise and resource use, these therapies are more like each other than they are like the other services or disease areas with which they are currently grouped.

The current MS-DRG procedure code assignments were made individually, per standard CMS process, as therapies were approved and in advance of understanding the resource utilization and product acquisition costs. For example, the hematopoietic stem cell gene therapies were mapped to MS-DRGs 016 and 017 because the care episode resembles an autologous stem cell transplant (autoSCT) for the treatment of blood cancers. ASTCT agrees that this was a reasonable interim step. We also, however, share the sentiment that CMS has noted in the last few IPPS rules: that new solutions are needed for cell and gene therapies. The final FY 2027 national unadjusted payment rates for those autoSCT MS-DRGs are \$44,435 and \$36,126, while the gene therapies mapped there have costs that range from \$2.2 million to \$4.25 million per patient. A few gene therapies have been assigned to MS-DRG 018, which has a higher base payment amount, but is not a strong clinical fit given that gene therapies are not immunotherapies.

In addition, other gene therapies have been assigned to non-Pre-MDC MS-DRGs based on the disease being treated vs. the clinical procedure and resource use. Leaving these cases where they are both underpays hospitals in real time and distorts future rate-setting by either (1) inflating the relative weights and overpaying non-similar cases mapped to those MS-DRGs or (2) causing the gene therapy cases to be trimmed from the data as extreme outliers and not contributing to an update to the relative weights, furthering the cycle of chronic underpayment.

Of the gene therapies ASTCT has identified in the list of procedure codes associated with this request, the gene therapies for sickle cell disease are the most likely of these to be



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administered to Medicare beneficiaries, due to a combination of disease prevalence and treatment age. The financial effect of the current assignments creates a very real access concern for Medicare beneficiaries, which is a statement ASTCT does not make lightly. Even with the 75 percent New Technology Add-on Payment (NTAP) that CMS finalized for the sickle cell therapies still in place, hospitals will lose hundreds of thousands of dollars per case due to the magnitude of the product cost and the built-in “up to” provisions included in Medicare payment calculations (i.e., up to 75% of the product cost and/or up to 80% of outlier costs).

After NTAP expires at the start of FY 2028, outlier payments will be the only mechanism hospitals have to address the gap between the MS-DRG base payment and the costs of care. On a multi-million-dollar therapy, the standard 20% loss associated with outlier payment, after losing the fixed-loss threshold amount, is not something that can be averaged out across other Medicare cases or recovered from non-Medicare margins.

ASTCT applauds the steps CMS has taken to recognize the unique opportunities—and challenges—associated with gene therapies by its creation of the CMMI Cell and Gene Therapy Access Model. We ask CMS to match the spirit of that model in Medicare, given that the model’s reach is currently limited to the Medicaid population.

To keep our request for a new MS-DRG consistent with CMS' classification principles, ASTCT proposes a Pre-MDC MS-DRG for gene therapies, with an adjustor mechanism that mirrors that which is currently utilized for MS-DRG 018 and allows a reduced payment for clinical trial cases or other circumstances where there is no product acquisition cost. Gene therapy is a field with many clinical trials and high acquisition costs, and this adjuster would prevent overpayment for trial cases while keeping an appropriate base payment for cases that incur product costs.

ASTCT has provided a list of the procedure codes associated with the gene therapies currently mapped to MS-DRGs for CMS to review. We note that this is not comprehensive across the list of FDA-approved cell and gene therapies, as some manufacturers have not sought ICD-10-PCS codes for the administration of their products, likely due to their typical use in non-Medicare populations and/or provision to outpatients.

Additionally, we have provided CMS with the full list of procedure codes available (to the best of our knowledge) despite knowing that some of the therapies associated with those codes have been pulled from the commercial market by their manufacturers since their codes were assigned to MS-DRGs. The diagnosis codes ASTCT supplied are meant to be representative of the disease states these therapies treat but are not comprehensive given the volume of codes that would require. We encourage CMS to do a more extensive review if the agency moves forward with this request, and ASTCT is ready to work with CMS to refine the logic and code list in an appropriate manner.

Finally, ASTCT notes that we realize that claims associated with rare disease therapies will stay low by the nature of the patient population, particularly in comparison to many of CMS' more common MS-DRGs and MDC categories. For autologous products, the path from cell collection to infusion can take most of a year. Our analysis of the currently available Medicare claims data confirmed low volume, returning fewer than 11 claims. ASTCT encourages CMS to move forward with a proposal of this nature regardless of low current volume; if CMS waits for the claims volume it usually requires within the current reimbursement framework, the barrier to care will remain, and likely worsen, given the upcoming expiration of NTAP.

Title, description and clinical type of the requested MS-DRG

ASTCT requests that CMS create a new Pre-MDC MS-DRG, potentially entitled "Gene Therapies," for one-time *in vivo* and *ex vivo* gene therapies that treat debilitating or life-threatening illnesses caused by genetic mutations. The growing number of FDA approvals for these products includes autologous hematopoietic stem cell therapies for sickle cell disease, beta thalassemia, and other inherited blood and immune disorders, as well as therapies for hemophilia, neurologic disease, and severe skin disease.

Although the diseases and delivery methods differ, all of these therapies are meant to make a long-lasting (and hopefully permanent) change to the patient's genetic code in service of modifying their disease course. These therapies also require specialized clinical teams for patient evaluation and administration, with advanced logistics, containment and engineering controls, special handling, and post-administration precautions. In clinical expertise and resource use, these therapies are more like each other than they are like the other services or disease areas where they are currently grouped.

This MS-DRG would contain both *in vivo* and *ex vivo* gene therapies intended to be one-time/permanent interventions for debilitating and/or life-threatening illnesses caused by genetic mutations. We have selected the Medical MS-DRG option but note that we are requesting a Pre-MDC MS-DRG that would also be inclusive of therapies that require surgical administration methods based on the scientific requirements of delivering the genetic modification to the target biological system.

MDC and severity level of the requested MS-DRG

ASTCT is requesting a Pre-MDC MS-DRG with no severity split levels.

Suggested principal diagnoses

ASTCT is requesting a Pre-MDC MS-DRG, which focuses on the procedure codes associated with the inpatient stay. As the application requires the provision of ICD-10-CM codes, ASTCT



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selected a sampling of diagnosis codes associated with the diseases treated by therapies addressed in the procedure code section. These are not meant to be comprehensive, however. We encourage CMS to conduct a more thorough and expansive review if the agency moves forward with the request.

D57.0 – Hb-SS disease with crisis	D61.03 – Fanconi anemia
D57.8 – Other sickle cell disorders	E70.81 – Aromatic L-amino acid decarboxylase (AADC) deficiency
D56.1 – Beta Thalassemia	D71.1 – Leukocyte adhesion deficiency
Q81.2 – Epidermolysis bullosa dystrophica	D66 – Hemophilia A
E75.25 – Metachromatic leukodystrophy	

Suggested Principal Procedures

ASTCT proposes that the new MS-DRG should include the following ICD-10-PCS codes. We have included their current MS-DRG assignments, per the ICD-10-CM/PC MS-DRG v44.0 Definitions Manual for easy reference. Procedure codes with an * indicate a non-operating room code.

DRG 016 Autologous Bone Marrow Transplant with CC/MCC **DRG 017 Autologous Bone Marrow Transplant without CC/MCC** **BONE MARROW TRANSPLANT**

NON-OPERATING ROOM PROCEDURES

30233C0*	Transfusion of Autologous Hematopoietic Stem/Progenitor Cells, Genetically Modified into Peripheral Vein, Percutaneous Approach
30243C0*	Transfusion of Autologous Hematopoietic Stem/Progenitor Cells, Genetically Modified into Central Vein, Percutaneous Approach
XW1337A*	Transfusion of Marnetegrane Autotemcel into Peripheral Vein, Percutaneous Approach, New Technology Group 10
XW133B8*	Transfusion of Betibeglogene Autotemcel into Peripheral Vein, Percutaneous Approach, New Technology Group 8
XW133G8*	Transfusion of Atidarsagene Autotemcel into Peripheral 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
XW133SB*	Transfusion of Mozafancogene Autotemcel into Peripheral Vein, Percutaneous Approach, New Technology Group 11
XW1437A*	Transfusion of Marnetegrane Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 10



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- XW143B8*** Transfusion of Betibeglogene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 8
- XW143F8*** Transfusion of Etuvetidigene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 8
- XW143G8*** Transfusion of Atidarsagene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 8
- XW143H9*** Transfusion of Lovotibeglogene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 9
- XW143J8*** Transfusion of Exagamlogene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 8
- XW143SB*** Transfusion of Mozafancogene Autotemcel into Central Vein, Percutaneous Approach, New Technology Group 11

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

T-CELL IMMUNOTHERAPY

OPERATING ROOM PROCEDURES

- XHR0XGA** Replacement of Head and Neck Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
- XHR1XGA** Replacement of Chest Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
- XHR2XGA** Replacement of Abdomen Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
- XHR3XGA** Replacement of Back Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
- XHR4XGA** Replacement of Right Upper Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
- XHR5XGA** Replacement of Left Upper Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
- XHR6XGA** Replacement of Right Lower Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
- XHR7XGA** Replacement of Left Lower Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10

NON-OPERATING ROOM PROCEDURES

- XW033FB*** Introduction of Valoctocogene Roxaparvovec-rvox into Peripheral Vein, Percutaneous Approach, New Technology Group 11

DRG 628 Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC or Insertion of Antibiotic-eluting Bone Void Filler

DRG 629 Other Endocrine, Nutritional and Metabolic O.R. Procedures with CC

DRG 630 Other Endocrine, Nutritional and Metabolic O.R. Procedures without CC/MCC

OPERATING ROOM PROCEDURES

XW0Q316 Introduction of Eladocogene exuparvovec into Cranial Cavity and Brain, Percutaneous Approach, New Technology Group 6

ASTCT has attempted to identify all relevant codes, but we encourage CMS to do its own review and seek input from stakeholders to ensure that codes have not been inadvertently missed. Additionally, ASTCT is aware that a few of the therapies associated with these procedure codes have been removed from the U.S. commercial market and/or have had their clinical trials discontinued. We have included them in this request in order to be as comprehensive as possible.

Discharge Status

ASTCT selected Not Applicable.

Category Request

ASTCT has selected the drug category for this new MS-DRG request because it is a Pre-MDC MS-DRG and the selected procedure codes are all for administration of the identified gene therapies. However, we acknowledge that some of the therapies require operating room procedures for product administration; therefore, the service category may also be applicable.

Anticipated Number of Claims Impacted

ASTCT utilized public information sources to provide estimates of potential claims across all payer types, as Medicare-specific information was unavailable.

Examples of potential volume from these sources are as follows:

- Casgevy (exagamglogene autotemcel): 117 cases (per FY 2025 IPPS Final Rule, 89 FR 70011; <https://www.govinfo.gov/content/pkg/FR-2024-08-28/pdf/2024-17021.pdf>)
- Lyfgenia (lovotibeglogene autotemcel): 40 cases (per FY 2025 IPPS Final Rule, 89 FR 70011; <https://www.govinfo.gov/content/pkg/FR-2024-08-28/pdf/2024-17021.pdf>)
- Zynteglo (betibeglogene autotemcel): reported 43 patient starts across all payer types in 2024 (<https://www.sec.gov/Archives/edgar/data/1293971/000129397125000009/blue-20241231.htm>)



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- Zevaskyn (prademagene zamikeracel): reported treating 12 patients since its FDA approval in April 2025 (<https://investors.abenotherapeutics.com/sec-filings/all-sec-filings/content/0001493152-26-037575/ex99-1.htm>)

Clinical Rationale for the Request

ASTCT requests that CMS create a new MS-DRG for one-time gene therapies given the evolution of the field and the increase in FDA-approved products that may be administered to Medicare beneficiaries. While gene therapies may be *ex vivo* or *in vivo*, they are all delivered with the intent of creating long-lasting (and potentially permanent) modifications to a patient's genetic code. Gene therapies require specialized clinical teams for product handling and administration. Their delivery requires advanced logistics for coordinated product shipment, containment and engineering controls and documentation, specialized handling and preparation services ahead of administration, and unique post-administration procedures including proper recordkeeping and disposal.

The therapies listed in our request all target genetic diseases, which share a commonality of causing severe disability and/or fatalities in affected individuals. While the disease states and administration methods vary, these therapies are more like each other in terms of clinical expertise and resource use than they are like their individual disease areas or otherwise similar clinical services.

Additionally, given the ongoing likelihood of frequent clinical trials associated with gene therapies, ASTCT asks that CMS structure payment associated with this potential new MS-DRG in a manner similar to MS-DRG 018 by allowing for a "no product cost" reporting option and payment adjuster. This adjustment would prevent overpayment for clinical trial cases while preserving an appropriate base payment for cases that include product acquisition costs.

Data Analysis

ASTCT reviewed Medicare Fee-for-Service claims data from fiscal years 2024 and 2025. We were expecting low volume given the timing of the FDA approvals and lengthy care episodes, which was confirmed with a finding of fewer than 11 claims. If CMS creates the new MS-DRG, we believe that the agency would need to remove clinical trial cases to develop an appropriate relative weight, as CMS currently does for MS-DRG 018. This will help avoid major under- or over-payments.

ASTCT appreciates CMS' review of our request and looks forward to engaging with the agency further on this issue.