



# AMERICAN SOCIETY OF HEMATOLOGY

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## 2024

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Submitted electronically via <http://www.regulations.gov>

RE: CMS-1808-P: 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 2025 Rates

Dear Administrator Brooks-LaSure:

The American Society of Hematology (ASH) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Medicare Program Proposed Rule Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2025 Rates (CMS-1808-P).

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. We are pleased to share comments on several policies as proposed in the rule, which include comments on:

- ICD-10-CM Codes for Duffy Null Status
- Proposed Changes to Severity Levels Social Determinants of Health – Inadequate Housing/Housing Instability
- Proposed Changes to the Calculation of the Inpatient New technology Add-on Payment for Gene Therapies Indicated for Sickle Cell Disease
- New Technology Add-on Payment Applications for Casgevy™ and Lyfgenia™
- Proposed Payment Adjustment for Certain Clinical Trial and Expanded Access Use for Immunotherapy Cases
- Payment for Graduate Medical Education

## ICD-10-CM Codes for Duffy Null Status

The Society would like to thank the agency, working in collaboration with the National Center for Health Statistics (NCHS), for creating and implementing new ICD-10-CM Z codes to describe Duffy null status. The new codes, requested by ASH, were created to ensure that the people who have lower absolute neutrophil count (ANC) due to Duffy phenotype are accurately documented within the medical record and are not considered to have “abnormal” ANC levels. The Society requested the new Z codes to ensure that reference ranges for neutrophil counts are

inclusive of populations that have a genetically lower, but completely normal, neutrophil count.

Specific Z codes will create accurate documentation of the Duffy status of individuals in a consistent and longitudinal manner. The new ICD-10-CM codes will be critical for proper reimbursement, accurate documentation, appropriate clinical care and management, and augmented ability to conduct research. Importantly, this accurate document of the Duffy status will decrease duplicative testing and allow for more precise medication administration, consistent with need. Again, we thank the agency for the support in this effort and the collaborative work with NCHS.

### **Proposed Changes to Severity Levels Social Determinants of Health – Inadequate Housing/Housing Instability**

ASH supports the agency's proposal to move seven ICD-10-CM Z codes that describe inadequate housing and housing instability from a non-complication or comorbidity (NonCC) classification to a complication or comorbidity (CC) classification. This proposal, if finalized, will allow CMS to capture and appropriately reimburse hospitals for the higher costs and resource utilization associated with patients experiencing housing inadequacy and housing instability. Through this change, CMS will recognize housing instability and inadequate housing as an indicator of increased resource utilization in the acute inpatient hospital setting. The ICD-10-CM codes included in this proposal are Z59.10, Z59.11, Z59.12, and Z59.19 to describe inadequate housing, and Z59.811, Z59.812, and Z59.819 to describe housing instability.

Understanding a patient's housing condition and status is an essential piece of information needed to ensure better health outcomes for patients. According to the National Health Care for the Homeless Council, people who are homeless or have unstable housing have higher rates of illness and die on average twelve years sooner than the general population of the United States.<sup>1</sup> When inadequate or unstable housing is coupled with living with a hematologic disease, the rate is likely even higher. Capturing data on housing will assist the hospital in planning for discharge and providing appropriate next steps, and by having these SDOH codes map to a DRG with higher payment will help account for the costs associated with providing this care.

### **Proposed Changes to the Calculation of the Inpatient New technology Add-on Payment for Gene Therapies Indicated for Sickle Cell Disease**

In the proposed rule CMS states that cell and gene therapies are “*among the costliest treatments to date*,” therefore CMS has proposed to provide additional payment under the existing new technology add-on payment (NTAP) policy, for cell and gene therapies used in the treatment of sickle cell disease (SCD). The agency has proposed to increase the NTAP payment for gene therapies when used in treating SCD from the current 65% to 75%. The add-on payment would be equal to the lesser of a) 75% of the costs of the new medical service or technology; or b) 75% of the amount by which the costs of the case exceed the standard DRG payment. We also note that the cost of the gene therapy is only one of the expenses associated with the treatment which include many exchange transfusions before the gene therapy is administered, use of plerixafor for stem cell collection, post therapy complications, and all the other services associated with providing a therapy as intensive and complicated as gene therapy.

The Society appreciates the agency's commitment to improve the access, quality, and experience of health care for the sickle cell disease (SCD) patient population as outlined in its Sickle Cell Disease Action Plan. This population of patients has historically been marginalized and the agency's commitment is vital to improving the SCD patients' health outcomes. The Society supports the plan that the CMS has articulated to help this community live longer, fulfilling lives. One of the pillars of the CMS SCD Action Plan is to promote access to innovative therapies. Within this goal, the agency has approved the Cell & Gene Therapy Access Model which will focus on the Medicaid population. ASH supports the development of this model and believes it has the potential to improve the lives of the people living with

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<sup>1</sup> National Health Care Center for the Homeless Council, *Homelessness & Health: What's the Connection? Fact Sheet*. February 2019. <https://nhhc.org/wp-content/uploads/2019/08/homelessness-and-health.pdf>. Accessed May 23, 2024.

SCD. However, SCD patients with traditional Medicare and those who are dually eligible with Medicare and Medicaid cannot participate in the Cell and Gene Therapy Access model and therefore will not benefit from it.

Given the agency's commitment to this patient population, ASH believes the agency must do more than increase the NTAP payment by 10% for gene therapies for individuals living with SCD. We note that even if the agency finalizes the proposed increase, it will not be sufficient to cover the expense of the gene therapies that may be provided to SCD patients. ASH remains concerned about the high cost of gene therapies; therefore, we request that the percentage of the NTAP payment for gene therapies be increased to 100% instead of the 75% as proposed by CMS. Appropriate reimbursement for these innovative therapies will help ensure that Medicare fee-for-service beneficiaries have access when the therapy is indicated for SCD patients. Providing an NTAP of 100% for this initial period will demonstrate the agency's same commitment to equity in the Medicare fee-for-service population that it is demonstrating through the creation of the Cell and Gene Therapy Model for the Medicaid population. Alternatively, if the agency cannot support a 100% NTAP payment, then the Society suggests using negotiations with the companies that produce gene therapy. ASH has longstanding policy supporting the federal government in negotiating prices directly with drug manufacturers. Given the high cost of these newly approved therapies, and the deficit that hospitals will incur even with the proposed 75% NTAP, ASH urges CMS to consider alternative pathways to support coverage and access.

While we certainly understand the agency's need to balance the cost of gene therapy within the entire Medicare budget, the costs may be lower than anticipated. CMS published 2016 data that fewer than 12,000 individuals living with SCD were Medicare fee-for-service beneficiaries. ASH's members have stated the population of SCD patients that may be candidates for SCD gene therapy is quite small, this coupled with the limited manufacturing capacity to produce the specialized products, which is currently estimated to be less than two hundred gene therapies per year, leaves only a small number of actual SCD gene therapy cases per year. We believe that it is reasonable for the agency to consider a higher NTAP percentage given this unique situation and coupled with agency's commitment to creating greater access to innovative therapies for the SCD patients for which the agency is responsible.

As we noted previously, we appreciate the agency's commitment to the SCD population, and given this commitment, the agency needs to reconsider its proposed policy of increasing the NTAP for SCD gene therapies from 65% to 75%. If the final NTAP payment is 75%, then for the facilities that provide gene therapy there will be a loss of 25% on a several million-dollar therapy. and many if not all facilities will not offer the therapy due to this potential loss. Although there will be a minimal number of patients who will receive gene therapy, the financial loss to the hospital may be untenable. This creates an access to care issue that the agency has stated a commitment to correcting. In the CMS SCD Action Plan, the agency articulates a goal of strengthening access in Medicaid for SCD patients. This goal will not be met if gene therapies are either underpaid or not offered due that underpayment in the Medicare program. As the agency is aware, payment policy within the Medicare program sets the standard for payment policy for other payers. There will be a downstream effect, and limited access to this transformative therapy should the agency finalize the 75% NTAP payment as proposed. The Society strongly encourages the agency to rethink its NTAP proposal, and instead finalize a 100% NTAP payment policy for SCD gene therapies.

Additionally, ASH believes that now is the time for the agency to consider future payment policy options for SCD gene therapies. In this proposed rule there are two SCD gene therapies that have applied for NTAP designation. The NTAP period is the appropriate time to collect data on the cost of providing gene therapies for SCD in the Medicare population, including the cost of preparatory care, supportive care, length of stay, and other costs besides the gene therapy itself incurred by the hospital. We believe this will allow the agency to then make informed decisions about future policy to cover the actual cost of this novel therapy. However, if there are no gene therapies being provided due to the inadequate NTAP payment, there will be no data available to then set appropriate rates after the NTAP period expires.

The Society is extremely concerned about payment for these high-cost innovative therapies after the NTAP expires. As noted in the proposed rule, the procedure codes for the two gene therapies that have applied for NTAP designations will map to MS-DRGs 016/017- autologous bone marrow transplant with CC/MCC and without

CC/MM, respectively, with reimbursement rates below \$50,000. Once the NTAP expires, again, if approved by CMS, the base payment rates these MS-DRGs will be woefully inadequate to sustain the provision of gene therapy for SCD. The Society urges CMS to consider alternative methods to reimburse for SCD gene therapies to support appropriate patient access, which will create greater access to these novel therapies and allow the agency to meet one of its goals as stated in the proposed rule. Per the rule (89 FR 36138) the agency states *“facilitating access to these gene therapies for Medicare beneficiaries with SCD may have the potential to simultaneously improve the health of impacted Medicare beneficiaries and potentially lead to long-term savings in the Medicare program.”*

The MS-DRG system was not structured to support the delivery of therapies as expensive as these gene therapies for SCD. ASH witnessed the challenges associated with establishing appropriate reimbursement for CAR T-cell therapy firsthand, and those treatments are significantly less expensive than SCD gene therapies. ASH urges CMS to begin considering how to appropriately pay for transformative gene therapies after the NTAP period concludes either by continuing a pass-through payment for the gene therapy itself, like the NTAP, or some other new mechanism. If the agency does not consider an innovative payment mechanism for this innovative therapy, it is likely that access will likely decrease or stop entirely for the Medicare population once the NTAP payments expire as hospitals will not be absorb the unreimbursed costs. ASH stands at the ready to work with the agency in developing payment policy that will allow SCD patients retain access to the novel gene therapies.

### **New Technology Add-on Payment Applications for Casgevy™ and Lyfgenia™**

Each year in the proposed rule, CMS publishes information on applications for which the agency is considering approval for the NTAP designation. In general, ASH has not endorsed one product over another, nor made product-specific comments about an NTAP designation. However, given the unique situation for the products under consideration in this proposed rule, we support the NTAP designations as proposed for Casgevy™ and Lyfgenia™. Our members want to provide their patients with gene therapy when indicated, and we believe that the NTAP designation will enable them to do so. As noted previously, the Society is willing to work with the agency on developing payment policies that will adequately capture the costs associated with gene therapy treatments after the NTAP expires.

### **Proposed Payment Adjustment for Certain Clinical Trial and Expanded Access Use for Immunotherapy Cases**

Effective in FY 2021, CMS created a new MS-DRG to capture hospital cases that includes procedures for CAR T-cell therapies. MS-DRG 018 has a relative weight that is reflective of the typical costs of providing CAR T-cell therapies in the inpatient setting. However, the agency recognized that including clinical trial cases in relative weight calculations would distort the weight of MS-DRG 018 because of the high cost of the CAR T-cell product, which is not included in clinical trial cases. Therefore, the agency created policy that excludes clinical trial cases from the weight calculations for CAR T-cell therapy.

The Society continues to support this CMS policy that will continue to exclude clinical trial cases, which do not include the cost of the CAR T-cell product itself, from the calculation of the relative weight from MS-DRG 018. The continuation of this policy ensures that the relative weight of the CAR T-cell MS-DRG is not artificially lowered and remains reflective of the true cost of providing CAR T-cell therapy.

### **Payment for Graduate Medical Education**

As part of ASH’s mission of fostering high-quality and equitable care, transformative research, and innovative education to improve the lives of patients with blood and bone marrow disorders, ASH is committed to addressing the shortage of hematologists. In 2019, ASH published findings from a three-year longitudinal study investigating the hematology workforce with a focus on recruitment to address the profound need for additional hematologists. The study found that medical school plays a role in shaping hematology-oncology fellows’ interest in pursuing careers in hematology and highlighted the importance of hematology mentors during medical education and training. Importantly, the study found that only a small percent of students showed interest in non-malignant hematology, also

known as classical hematology and encompasses blood diseases and conditions, such as SCD, hemophilia, and other bleeding and clotting disorders – serious conditions that affect millions of individuals. This information has motivated ASH to proactively address the supply of hematologists, particularly in classical hematology.

ASH created the Hematology-Focused Fellowship Training Program (HFFTP) to help increase the number of fellowship programs that prioritize training and careers in hematology. The HFFTP is a pathway that offers physicians the opportunity to pair comprehensive classical hematology training with career-enhancing education in several related areas. Funded entirely by ASH, ten new hematology-focused fellowship tracks were created at nine institutions across the country. The HFFTP aims to strengthen the next generation of hematologists, with an initial goal of producing fifty new academic hematologists by 2030.

It is within this context that we provide comments on the GME-related policies in this rule.

*Proposed Distribution of Additional Residency Positions Under the Provisions of Section 4122 of Subtitle C of the Consolidated Appropriations Act, 2023*

In the rule, CMS is proposing to distribute two hundred new GME slots for FY 2026, as required under section 4122 of the Consolidated Appropriations Act of 2023. By law, at least half of the positions must be allocated to psychiatry or psychiatry subspecialty residency programs, and CMS will reward all qualifying hospitals that submit applications on time to receive an award of up to 1.00 full-time employee. For remaining GME slots, CMS will prioritize the distribution based on the health professional shortage area (HPSA) score associated with the program for which each hospital is applying to help bolster the healthcare workforce in rural and underserved areas.

ASH appreciates that CMS wishes to bolster the physician workforce in rural and underserved areas and recognizes that CMS is statutorily constrained in its distribution methodology; however, ASH has concerns regarding the methodology and geographic boundaries used to calculate HPSA scores and recommend CMS consider looking at distributing slots in areas where there are high rates of maternal mortality. When considering residency and fellowship positions, we believe it would be beneficial to take this data into account, coupled with geographic areas with high rates of SCD and other hemoglobinopathies. This approach might not always align with traditional HPSA delineations, but we believe it is worth exploring given the serious hematologic needs of these patients.

*Proposed Modifications to the Criteria for New Residency Programs and Requests for Information (RFI)*

ASH recognizes that CMS has a long-standing policy requiring residency programs to meet specific criteria to be classified as a new program. This classification is important because it determines if a hospital can receive additional funding through increased GME cap slots. As Congress considers expanding funding for Medicare GME, we appreciate CMS' intent to define what constitutes a new residency or fellowship program to avoid situations where a program at an existing teaching hospital would be transferred to a new teaching hospital, resulting in cap slots being created for identical programs at two separate hospitals.

Regarding the newness of residents in the classification of a new program, CMS is proposing that at least 90 percent of trainees must not have prior training in the same specialty for a residency program to be considered new. ASH supports this proposal and agrees that if more than 10 percent of trainees have training experience in that specialty or are transferred from another program in the same specialty, the new residency program should not be eligible for new cap slots. This will ensure that funding is provided for genuinely new residency programs.

Additionally, CMS is seeking feedback on the newness of faculty and program directors related to the classification of a new program. Specifically, the agency seeks input on what proportion of faculty should have no previous experience teaching in the same specialty. CMS is considering policy requiring that half of the teachers of a program must be new, meaning they have not taught in that specialty program before, for the program to be considered new and eligible for cap slots. ASH strongly disagrees with this approach. We believe it would be in the best interest of the program to benefit from having faculty members with extensive teaching experience in the specialty. The complexity and rigor of the curriculum necessitate faculty and program directors who have a proven history of success

with effective teaching techniques. Expertise and familiarity with the specialty is invaluable in guiding residents and fellows, thereby enhancing the education, training, and quality of care provided within the program. Moreover, implementing a threshold of this kind would be in direct conflict with the Accreditation Council for Graduate Medical Education's (ACGME) qualifications for program directors, which require program directors to have "specialty expertise and at least three years of documented educational and/or administrative experience."<sup>2</sup>

Furthermore, it is important to highlight that implementing restrictions like these would be especially harmful to residency programs and teaching hospitals in rural and underserved areas where recruitment and retention may be more difficult. Residency programs in rural areas are often smaller in comparison to those in urban areas. These programs face unique challenges in recruiting and retaining physicians, and they have greater financial constraints and limited resources. For these reasons, we urge CMS not to implement the proposed thresholds for faculty and program directors.

CMS is also investigating and seeking feedback on reasons for needing two separately approved programs at the same hospital. ASH believes that there may be certain instances where this would be appropriate for the purposes of training. For example, there are some teaching hospitals at which residents who are sponsored by different institutions train, and hospitals may collaborate with multiple medical schools or residency programs based on the facilities and resources in each area. It is important to note that this may be more common in metropolitan areas where teaching hospitals may share facilities or other resources for training.

Correspondingly, we recognize that CMS is requesting feedback on the appropriateness of resident "commingling" between new and existing programs. We do not believe this happens frequently in institutions around the country; however, this practice should be encouraged, rather than prohibited. While this is not a common practice, it would be more than appropriate for internal medicine or pediatric residency and hematology fellowship programs to share didactics and educational resources.

ASH thanks CMS for the opportunity to share these comments on the IPPS proposed rule for FY2025. Should you have any questions or require further information, please contact Carina Smith, Manager, Health Care Access Policy, at [casmith@hematology.org](mailto:casmith@hematology.org).

Sincerely,



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<sup>2</sup> [https://www.acgme.org/globalassets/pfassets/programrequirements/cprresidency\\_2023.pdf](https://www.acgme.org/globalassets/pfassets/programrequirements/cprresidency_2023.pdf)