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June 17, 2022

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Centers for Medicare & Medicaid Services
U. S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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Dear Administrator Brooks-LaSure:

Secretary

Isabelle Riviere, PhD
Memorial Sloan Kettering Cancer Center

The American Society of Gene and Cell Therapy appreciates the opportunity to comment on CMS-1771-P, the proposed rule for Medicare's Hospital Inpatient Prospective Payment System (IPPS) for 2023.

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About ASGCT

The American Society of Gene and Cell Therapy (ASGCT) is a nonprofit professional membership organization comprised of more than 5,500 scientists, physicians, patient advocates and other professionals. Our members work in a wide range of settings including universities, hospitals, government agencies, foundations, and biotechnology and pharmaceutical companies. Many of our members have spent their careers in this field performing the underlying research that has led to today's robust pipeline of transformative therapies. A core portion of ASGCT's mission is to advance the discovery and clinical application of genetic and cellular therapies to alleviate human disease. To that end, ASGCT supports Medicare payment policies that foster the adoption of, and patient access to, new therapies, which thereby encourage continued development of these innovative treatments. The Society's support of sufficient and appropriate reimbursement levels to providers to facilitate patient access does not imply endorsement of any individual pricing decisions.

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2023 Proposals

Comment Solicitation on Possible Mechanisms to Address Rare Diseases and Conditions Represented by Low Volumes Within the MS-DRG Structure

In the proposed rule, CMS solicits comments "to explore possible mechanisms through which we can address rare diseases and conditions that are represented by low volumes in our claims data."

ASGCT applauds CMS for issuing this comment solicitation. Cell and gene therapies are re-shaping the landscape of treatment for rare diseases, offering unprecedented opportunities to impact the lives of patients who suffer from them. However, cell and

gene therapies also represent a paradigm shift; rather than treating a disease with a lifetime of medications, cell and gene therapies typically involve a limited number of treatments. Medicare's traditional payment system must be modified to create greater certainty in the marketplace to ensure no patient experiences challenges in accessing the therapies. CAR T-cell therapy provides a case study in the challenges of the current IPPS system. In the initial years of coverage, CMS opted to assign CAR T-cell therapy to DRG 016, along with providing a New Technology Add-on Payment (NTAP). ASGCT supported that approach as CMS collected additional data to support the proper weighting of a stand-alone DRG. In 2019, ASGCT foresaw the need in future years to create a new DRG specifically for cases involving CAR T-cell therapies, based on the availability of additional data that is more accurately and consistently reflective of actual costs to providers.

Consider a new reimbursement methodology that establishes separate payment for low volume high-cost drugs.

- As noted by CMS, providers face challenges in providing access to orphan drugs in the Medicare hospital inpatient setting as payment may be insufficient to cover the costs of these drugs. Medicaid inpatient payment policies create the same problem. Medicare's traditional payment system must be modified to create greater certainty in the marketplace to ensure no patient experiences challenges in accessing the therapies.
- We recommend that CMS invoke the authority of CMMI to establish new, alternative payment models for gene and cell therapies, outside of the constraints of the IPPS. The uncertainty and confusion associated with the CAR T-cell experience had a significant impact on patients, providers, and manufacturers alike. By establishing a new, value-based payment model, CMMI could establish a clearer path to coverage and payment policy that can improve patient access.
- To ensure appropriate access to these new medicines we urge CMS to explore seamless payment for these therapies across Medicare and Medicaid.

Consider New Technology Add-On Payment (NTAP)

We recommend additional reforms to optimize the NTAP system to accommodate the next wave of technologies.

- Quarterly review of NTAP-qualifying products approved by the FDA, regardless of the approval pathway. The NTAP should be immediately accessible for new technologies coming to market and not be tied to an annual rulemaking cycle. The current NTAP process window (i.e., FDA approval requirement of July 1) is much too narrow (as CMS has already recognized for certain antimicrobial, antibacterial, and antifungal products).
- The ability for manufacturers to apply for NTAP when they have data to complete an NTAP application and CMS to "pend" those applications deemed to meet the applicable NTAP criterion until the product is marketed.
- An increase in the cap for NTAP amounts from 65 percent to 100 percent or a uniform NTAP equal to the product acquisition cost for gene and cell therapies. We appreciate the recent actions of CMS to increase the NTAP cap in FY 2020 from 50 percent to 65 percent; however, even the 65 percent level would not be expected to sufficiently fill the gap in reimbursement to providers.
- NTAP eligibility for three full years to allow the increased collection of cost data for the small populations often treated by gene and cell therapies, prior to rate-setting, or establishing new MS-DRGs prior to NTAP expiration.
- Continue to recognize the limited patient populations (especially for products indicated for rare diseases) when considering the number of cases (excluding clinical trials cases) sufficient to establish a new DRG. Because the process for establishing new MS-DRGs is dependent upon CMS having sufficient data on charges for therapy, the creation of DRGs for gene and cell therapies for rare diseases with small populations can be delayed well past the NTAP period. If CMS intends to pay for future gene and cell therapies in a similar fashion to CAR T cell therapy through NTAP assignment as applicable, followed by the establishment of new DRGs, CMS must have flexibility in its metrics for such establishment.



Further Stakeholder Engagement Related to Gene and Cell Therapies

In the proposed rule, CMS indicates it received “additional feedback and suggestions” relating to CMS commitment to “continue engaging with stakeholders on additional options for consideration in this field of cellular and gene therapies” in the FY 2022 IPPS. In response, CMS indicates it intends to “continue engaging with stakeholders by sharing updates from our analysis of claims data as we examine and explore potential refinements for these therapies under the IPPS.”

ASGCT applauds CMS for committing to a continued dialogue with stakeholders related to Medicare payment for cell and gene therapies. The field of cell and gene therapies remains in its relative infancy. However, in the handful of years CMS has been faced with setting Medicare payment policy for CAR T-cell therapy, the path from FDA approval to sustainable payment solutions has demonstrated how the nature of gene and cell therapy challenges the constraints of the program. We urge CMS to continue engaging with stakeholders on this matter in an open and transparent fashion.

Thank you for the opportunity to submit comments on Medicare’s proposed update to inpatient payments in FY 2023. Please contact Margarita Valdez Martínez, Director of Policy and Advocacy, at mvaldez@asgct.org, with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'David Barrett', is written over a light blue horizontal line.

David Barrett, JD
Chief Executive Officer