American Society of Gene + Cell Therapy



October 10, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U. S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Gene and Cell Therapy (ASGCT), I am writing to offer our continuing concerns with changes that the Centers for Medicare & Medicaid Services (CMS) made to the New Technology Add-on Payment (NTAP) in the Fiscal Year 2024 Inpatient Prospective Payment System (IPPS).

For many Medicare beneficiaries with chronic conditions or other life-threatening conditions, gene and cell therapies offer the potential of life-altering improvements. ASGCT remains concerned that the change CMS finalized could significantly impact the ability of Medicare beneficiaries to access these new therapies as they come to market, creating unnecessary bureaucratic barriers to care.

**About ASGCT**

The American Society of Gene and Cell Therapy (ASGCT) is a nonprofit professional membership organization comprised of more than 6,000 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.

**Changes to the New Technology Add-on Payment**

In a rule finalized this summer, CMS made significant changes to the NTAP that take effect in FY 2024. Specifically, CMS now requires that drugs have an FDA marketing authorization deadline of May 1, rather than July 1, to be considered for the NTAP. In changing this deadline for FDA approval, CMS has placed new limitations on which products can be considered for the NTAP, which may have significant impact on the ability of Medicare beneficiaries to access new therapies coming to market.

The case study of Chimeric Antigen Receptor (CAR) T-Cell Therapy provides a meaningful example of the impact of NTAP policy. In 2020, CMS took the step of establishing a new MS-DRG specifically for CAR T-cell therapy, despite the relatively low volume of cases applicable to the DRG. However, before CMS established the DRG – CMS awarded the NTAP for two CAR T-cell therapy products. This decision provided a critical access bridge for these products, ensuring that providers could continue to make the products available to patients. Had CMS not offered the NTAP for these two products, providers seeking to make CAR T-cell therapy available to Medicare beneficiaries would have faced significant challenges. These challenges very well could have led to reticence of some providers to offer the treatment.

In the final rule, CMS described the rationale for the changes. CMS noted the "ever-increasing complexity and number of applications" for the NTAP, including those "lacking critical information" needed to evaluate the criteria. CMS specifically noted that the purpose of the rule change was not to "reduce the number of applications or decrease CMS' workloads." We appreciate CMS' initiative to clarify the intent of the policy change in the final rule. However, we remain concerned with its ultimate impact. While CMS' intention may have been to facilitate greater opportunities for transparency and information sharing, the net impact of the policy change may be to exclude therapies from the NTAP that might otherwise have been eligible if they received FDA approval between May 1 and July 1.

In response to comments about beneficiary access, CMS stated that "patient access to these technologies should not be adversely affected if a technology does not qualify to receive new technology add-on payments, as CMS continues to pay for new technologies through the regular payment mechanism established by the MS-DRG methodology." We remain concerned that CMS has significantly underestimated the downstream impact to beneficiary access associated with restricting the products eligible for the NTAP. To ensure seamless patient access, we urge CMS to provide a

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grace period or a waiver of this new requirement for a complete and active FDA marketing application authorization for this first year of implementation.

Please do not hesitate to contact us if we can be of assistance in offering the perspective of clinicians, manufacturers, providers, and others involved in the development and implementation of gene and cell therapies. Please contact Margarita Valdez Martínez, Director of Policy and Advocacy, at mvaldez@asgct.org, with any questions.

Sincerely,

David Barrett, JD
Chief Executive Officer