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June 28, 2021

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Dear Administrator Brooks-LaSure:

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The American Society of Gene and Cell Therapy appreciates the opportunity to comment on CMS-1752-P, the proposed rule for Medicare's Hospital Inpatient Prospective Payment System (IPPS) for 2022.

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About ASGCT

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The American Society of Gene and Cell Therapy (ASGCT) is a nonprofit professional membership organization comprised of more than 4,600 scientists, physicians, and other professionals working in gene and cell therapy in settings such as universities, hospitals, and biotechnology 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.

CEO

David M. Barrett, J.D.

2022 Proposals

Expansion of Procedures Included in MS-DRG 018

In the FY 2022 proposed IPPS, CMS has proposed to broaden the procedure codes that would be assigned to MS-DRG 018, as well as to modify the name of the MS-DRG from “Chimeric Antigen Receptor (CAR) T-Cell Immunotherapy” to “Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies.” ASGCT believes that Medicare payment policy should ensure beneficiary access to both new and existing gene and cell therapies, as well as providing an environment that consistently fosters innovation of lifesaving treatments. We appreciate that the Agency is looking forward to products in the pipeline, like tumor-infiltrating lymphocyte (TIL) therapies, and making changes to the reimbursement system in advance. However, we believe the proposed changes could impact Medicare reimbursement to providers who administer CAR T-cell therapy, as well as other cell therapies in the pipeline.

We understand that CMS is faced with a challenging landscape in incorporating the administration of new gene and cell therapies into the IPPS and recognizes that CMS is proposing assignment of tumor-infiltrating lymphocyte (TIL) therapies to the most similar DRG that covers similar clinical characteristics and comorbidities—MS-DRG 018. However, whether for TIL therapies or other pipeline products, we urge CMS to consider the following factors when determining a permanent payment mechanism:

- patient diagnosis and product indication
- cell collection methodologies (tissue biopsy, pheresis, etc.)
- product administration methodologies
- patient clinical care regimes and durations
- product safety and toxicity profiles that impact inpatient care and follow-up

Society experts note that there are distinct and important differences in these factors between TIL therapies and CAR T-cell therapies that may support reconsideration of the DRG assignment after a product is approved by the FDA and is used to treat Medicare beneficiaries. These include the indications (solid vs. blood cancers), cell collection methodology (tissue biopsy vs. pheresis), and safety and toxicity profiles.

We recommend further consideration of the appropriateness and patient access implications, based on these factors, before grouping the two types of therapies together on a long-term basis. We also suggest that if CMS changes the name of DRG 018 to include TIL therapies upon their initial approval, as proposed, that the name of the DRG more clearly reflect the specialized products within. ASGCT believes the most accurate name for this DRG would be “Immune Effector Cell Therapies.”

Exclusion of clinical trial cases in calculating relative weight of MS-DRG 018

ASGCT supports CMS' decision to continue excluding clinical trial cases from the payment calculations used to set the relative weight of MS-DRG 018. ASGCT appreciates CMS' decision to exclude clinical trial cases in FY 2021 and urges CMS to continue doing so. Given the relatively small number of cases available to CMS for the purposes of calculating MS-DRG weights, the importance of a case pool that accurately reflects the cost of the therapies is essential. To accomplish this goal, ASGCT supports the proposed continued exclusion of cases with a clinical trial indicator (Z00.6) or with standardized drug charges below \$373,000 from the FY2022 rate-setting process. We also appreciate that CMS included revenue code 0891 in FY2021 in the definition of "standardized drug charges of less than \$373,000" utilized to exclude clinical trial claims from rate-setting. (Revenue code 0891, called *Special Processed Drugs – FDA Approved Cell Therapy*, went into effect in April 2019.)

Future Considerations

ASGCT greatly appreciates CMS' willingness to establish a new DRG explicitly for CAR T-cell therapy payment in the FY 2021 rule and in utilizing a new methodology of excluding clinical trial cases. ASGCT is optimistic that this approach will afford CMS the opportunity to more accurately reimburse providers for CAR T-cell therapy administration based on data specific to providing such therapy. We also appreciate CMS' attention to the cell therapy pipeline and anticipation of new TIL therapies.

With 1,153 gene and cell therapies in clinical trials in the United States for oncology indications,¹ many new therapies may be coming to market that have significant Medicare populations. The indications, patient populations, procedures for cell collection and administration, and risk profiles of these therapies may vary significantly. The Society believes these factors should all be weighed when determining the appropriateness of adding new products into existing MS-DRGs on a long-term basis.

As new gene and cell therapies come to market for these and non-oncology indications, it is incumbent on CMS to continue to evolve payment policy to keep pace with a changing marketplace, while ensuring access for Medicare beneficiaries to the products most appropriate for each individual, including previously approved therapies. ASGCT has expressed concerns that current Medicare reimbursement mechanisms for new

¹American Society of Gene and Cell Therapy. (2021) Clinical Trials. <http://www.asgct.org/clinicaltrials>.

medical products are outdated in their ability to accommodate the multiple gene and cell therapies in the pipeline that consist of a one-time biologic product, plus services to provide the therapy. While the Society has therefore raised the long-term question of whether the IPPS is the most appropriate system for expedient reimbursement of new products, we have specific recommendations on how the current system could be improved if it is to be retained:

- NTAP reform. ASGCT supports the use of NTAPs in the current system for all products that meet the statutory and regulatory criteria for such payment. However, additional reforms are recommended to optimize this system. ASGCT therefore recommends:
 - 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).
 - 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. The Society appreciates 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 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 as described below.
- Establishment of new MS-DRGs. Because the process for establishing new MS-DRGs is dependent upon CMS having sufficient data on charges for a 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 for products that differ from CAR Ts, CMS must 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. ASGCT encourages

CMS to establish new DRGs prior to NTAP expiration and to clearly identify the case parameters to utilize to prevent patient access challenges.

Thank you for the opportunity to submit comments on Medicare's proposed update to inpatient payments in FY 2022. Please contact Betsy Foss-Campbell, Director of Policy and Advocacy, at bfoss@asgct.org, with any questions.

Sincerely,



David Barrett, JD
Chief Executive Officer