June 24, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
The Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC  20001

Dear Administrator Verma:

The National Comprehensive Cancer Network® (NCCN®) writes to comment on the Centers for Medicare & Medicaid Services (CMS) Fiscal Year (FY) 2020 Hospital Inpatient Prospective Payment System (IPPS) proposed rule as it relates to NCCN’s mission of improving and facilitating, quality, efficient, and accessible cancer care.

As an alliance of 28 leading academic cancer centers in the United States that treat hundreds of thousands of patients with cancer annually, NCCN is a developer of authoritative information regarding cancer prevention, screening, diagnosis, treatment, and supportive care that is widely used by clinical professionals and payers alike. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. NCCN Guidelines® and Library of Compendia products help ensure access to appropriate care, clinical decision-making, and assessment of quality improvement initiatives.

Since 2008, CMS has recognized the NCCN Drugs & Biologics Compendium (NCCN Compendium®) as a mandated reference for establishment of coverage policy and coverage decisions regarding the use of drugs and biologics in cancer care. The NCCN Guidelines are transparent, continuously updated, available free of charge online for non-commercial use and through a multitude of HIT vendors, and NCCN Guidelines and Library of Compendia products are utilized by commercial payers that represent more than 85 percent of covered lives in the United States.

NCCN Member Institutions are at the forefront of administering Chimeric Antigen Receptor (CAR) T-cell therapy. Our Member Institutions served as leaders during the clinical trial phase of these products and, following the Food and Drug Administration (FDA) approval of tisagenlecleucel and axicabtagene cileoleucel, comprise a majority of the centers across the nation accredited and qualified to provide CAR T-cell therapy commercially. NCCN has serious concerns about cancer centers’ ability to sustain access to this life-saving therapy under the current reimbursement mechanism. NCCN Member Institutions cite monetary losses in the several hundreds of thousands for the procurement of CAR T-cell products, their administration, and management of toxicities associated with the therapy. NCCN is grateful
for the opportunity to provide comment to CMS and will focus our remarks on provisions that will have the most immediate impact on preserving patient access to high-quality cancer care by appropriately incentivizing physicians and hospitals to utilize this technology.

**MS-DRG-16 (Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy) and Continued NTAP Through FY 2020**

In the 2019 IPPS finalized rule, CMS worked to address the financial burden experienced by providers offering CAR T-cell therapy through the implementation of a new Medicare Severity Diagnosis Related Groups (MS-DRG) of 016 — Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy — paired with a New Technology Add-on Payment (NTAP) for CAR T-cell Therapy. CMS revisits the MS-DRG for CAR T-cell therapy and the designation of both FDA-approved CAR T-cell products as “new technologies” in the 2020 proposed rule. Specifically, CMS seeks comment on withholding modification of the MS-DRG-16; citing concerns of premature clinical and reimbursement data. CMS further notes that for the purposes of NTAP reimbursement for cancer centers, they propose to continue the designation of both commercially available CAR T-cell products as “new technologies”.

NCCN agrees with the American Society of Hematology (ASH) and the American Society of Transplantation and Cellular Therapy (ASTCT) that the continuation of unadjusted payment for CAR T-cell, MS-DRG-16, is reasonable and appropriate. Although reimbursement is separate from coverage, NCCN hopes the pending National Coverage Decision (NCD) with Coverage with Evidence Development (CED) proposal for CAR T-cell therapy will be designed with significant consideration to leverage the evidence collected to expeditiously create a new MS-DRG or modify MS-DRG-16. NCCN also strongly supports the continued designation of YESCARTA™ and KYMRIAH™ as “new technologies” and their eligibility for NTAP reimbursement in FY 2020.

**Chimeric Antigen Receptor (CAR) T-Cell Therapy Reimbursement for Prospective Payment System (PPS) and PPS-Exempt Cancer Centers**

NCCN applauds CMS’ recognition of the current reimbursement challenges and continual steps taken to resolve reimbursement gaps under IPPS. In the FY 2020 IPPS proposed rule, CMS seeks comment on the appropriateness of an increase of the NTAP from 50 percent to 65 percent of the costs of the technology; or, from 50 percent to 65 percent of the amount by which the costs of each case exceed the standard DRG payment. This adjustment would increase the maximum add-on payment amount from $186,500 per case (half the cost of the product) to $242,450 per case. However, increasing the maximum new technology payment for CAR T-cell products to $242,450 will not sufficiently cover the expenditures amassed by cancer centers. With this issue in mind, NCCN respectfully asks that CMS consider increasing the NTAP to 80 percent to sustain the feasibility of CAR T-cell therapy in Prospective Payment System (PPS) cancer centers.
CMS also requests public comment on the viability of utilizing a Cost-to-Charge Ratio (CCR) when determining payments to PPS-exempt cancer centers for CAR T-cell therapies. NCCN supports a 1.0 CCR payment mechanism for dedicated cancer centers in relation to CAR T-cell therapy. Additionally, NCCN concurs with the Alliance of Dedicated Cancer Centers (ADCC) that a CCR of 1.0 for CAR T-cell therapy would be most effective if joined with improvement processes for requesting adjustments to CAR-T reimbursement under the Tax Equity and Fiscal Responsibility (TEFRA). An expedient adjustment process would provide real-time relief for exempt centers managing patients with severe cases of toxicity associated with the treatment. NCCN asks that CMS continue to build a defined funding path for exempt centers, as it is critical to ensuring appropriate access to CAR T-cell therapy for all Medicare beneficiaries.

**Alternative Payment Models for Cell/Gene Therapies and Clinical Trial Cases**

Lastly, public comment is sought on alternative payment methodologies for CAR T-cell therapy. CMS specifically notes their interest in value-based care models and asks for comment on how alternative methodologies will impact drug spend, access to care, and whether clinical trial data should be used in the formulation of relative weights for a new payment methodology or MS-DRG for CAR T-cell therapy. NCCN is largely supportive of alternative payment models for CAR T-cell Therapy. NCCN requests that CMS prioritizes protecting patient access to high-quality cancer care when evaluating alternative reimbursement models. NCCN is also supportive of the removal of CAR-T clinical trial claims data from the development of relative weights for MS-DRG 016 and future CAR-T rate setting. NCCN believes that this claims data, which does not include the cost of acquiring the product, would skew pricing data towards an insufficient rate.

NCCN appreciates the opportunity to provide feedback on the CMS FY 2020 IPPS proposed rule. NCCN urges CMS to address CAR T-cell reimbursement issues in the finalized rule through a CCR of 1.0 that is not implemented against the TEFRA cap, and the adjustment of the NTAP to 80 percent. We welcome the opportunity to discuss our comments further and look forward to working together to ensure Medicare beneficiary timely access to high-quality cancer care.

Sincerely,

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