June 21, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-1694-P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates

Dear Administrator Verma:

The National Comprehensive Cancer Network® (NCCN®) is pleased to comment on the Centers for Medicare & Medicaid Services (CMS) Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates as it relates to NCCN’s mission of improving the quality, effectiveness, and efficiency of cancer care so that patients can live better lives.

As an alliance of 27 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. The 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 their derivatives help ensure access to appropriate care, clinical decision-making, and assessment of quality improvement initiatives.

Additionally, 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 and in 2016, NCCN was recognized by CMS as a qualified provider-led entity (PLE) for the Medicare Appropriate Use Criteria (AUC) Program. Through this qualification, CMS recognizes NCCN as a group qualified to develop AUC and establish policy and decision-making for diagnostic imaging in patients with cancer. NCCN Imaging AUC™ are available free of charge to registered users of NCCN.org and can be accessed at NCCN.org/ImagingAUC.
CAR-T Reimbursement Proposals

NCCN Member Institutions have been at the forefront of providing CAR T-Cell therapy throughout the clinical trial phase of development and now comprise a significant majority of the centers across the nation that are trained, accredited, and qualified to provide CAR T-Cell Therapy post-FDA approval. NCCN has heard from a variety of stakeholder groups that the current Medicare reimbursement, for PPS and PPS-exempt cancer centers, is reportedly several hundreds of thousands of dollars below the actual cost for procurement and administration of CAR T-Cell therapy. In addition to the high cost of the drug, CAR T-cell administration can be accompanied by significant toxicities including cytokine release syndrome (CRS), neurotoxicity, prolonged cytopenia, and hypogammaglobulinemia. The intensive and specialized services required to manage these toxicities adds significant additional cost, further compounding reimbursement challenges.

The NCCN Clinical Practice Guidelines for Acute Lymphoblastic Leukemia (ALL) includes CAR T-cell therapy as a Category 2A recommendation for patients under the age of 26 with B-cell ALL who have refractory disease or two or more relapses and failures of two prior lines of therapy. The NCCN Clinical Practice Guidelines for B-Cell Lymphoma recommend CAR T-cell therapy as a Category 2A recommendation for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including Diffuse Large B-Cell Lymphoma (DLBCL) Not Otherwise Specified (NOS), primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Given the significant reimbursement challenges outlined above, NCCN remains concerned about the ability of patients with Medicare to access the care outlined in our guidelines.

NCCN applauds and thanks CMS for recognizing the access issues posed by the current reimbursement challenges in the provision of CAR T-Cell therapy. In the 2019 IPPS proposed rule, CMS requests feedback on a number of potential pathways to CAR T-cell reimbursement. Whichever solution CMS chooses to enact must work for both hospitals in the Prospective Payment System as well as Exempt centers in order to ensure patient access for Medicare beneficiaries across the country is not impeded.

NCCN supports the implementation of a Cost to Charge Ratio (CCR) of 1.0 payment mechanism for PPS Exempt centers to ensure adequate reimbursement that does not impede patient access. NCCN agrees with the Alliance of Dedicated Cancer Centers (ADCC) that this mechanism would be best implemented through standard cost-reporting processes outside of the TEFRA cap, which would enable the agency to identify the cost to the hospital of acquiring the therapy and reimburse for it accordingly. NCCN endorses the steps outlined in ADCC’s letter to accomplish this. To ensure adequate reimbursement that does not impede patient access at PPS hospitals, NCCN
supports the American Society for Blood and Marrow Transplantation (ASBMT) and the American Society of Hematology (ASH) recommendation that CMS assign CAR T-cell cases to MS-DRG 016 as proposed and utilize its authority to pay separately for the CAR-T products based on the average sales price (ASP). Paying separately for the product will complement the approach at exempt hospitals and will avoid inappropriately adjusting the payment for the CAR-T cells for factors, such as differences in labor costs or teaching hospital status, that are not expected to affect the price of the CAR-T product. NCCN additionally notes that appropriate reimbursement of CAR T-Cell therapy should not be used to negatively impact reimbursement in other hospital services which may impede patient access to care.

The combination of a CCR of 1.0 for PPS Exempt hospitals and the assignment of MS-DRG 016 combined with separate payment for the CAR T Products based on ASP is a comprehensive and complementary approach to ensuring appropriate patient access to CAR T-cell therapy. NCCN is in alignment with ASBMT and ADCC and hopes that CMS will consider this as a sustainable and reasonable solution to the current challenges surrounding CAR T reimbursement and access.

**Quality Measures**

In the 2019 IPPS Draft Rule, CMS proposes to remove four cancer measures and add one cancer measure for PCQHR (exempt) cancer hospitals. Additionally, CMS proposes two measures for future inclusion. NCCN reviewed the proposals and is pleased to provide feedback. NCCN supports the proposed removal of measures PCH-14, PCH-16, PCH-17, and PCH-18 as a way to reduce reporting burden without impacting the quality of patient care. Additionally, NCCN supports the addition of the 30 Day Unplanned Readmissions for Cancer (NQF #3188) for exempt cancer centers.

CMS also requests feedback on measures considered for future inclusion. NCCN appreciates that CMS is evaluating additional measures to ensure quality cancer care and is pleased to provide feedback on these measures. NCCN has concerns that the inclusion of “Risk-adjusted morbidity and mortality for lung resection, lung cancer” may have negative implications for lung cancer care. In the absence of a lung cancer risk-adjusted model, NCCN is concerned that this measure may penalize centers that choose to serve more complex, high-risk patients. CMS also seeks feedback on incorporating “Shared Decision Making” as a future measure. While NCCN supports Shared Decision Making as an essential component of high-quality cancer care, we have concerns that the measure may pose significant tracking, reporting, and validation challenges. Collecting this data would require significant changes to how Electronic Health Records are currently structured. Additionally, in the absence of tools to validate the fulfillment of this measure, we have concerns that it may not result in the practice change it is intended to achieve. As CMS considers these and other future measures for
inclusion, NCCN is happy to provide its expertise to CMS to achieve the mutual objective of high value, efficient, high quality care for patients with cancer.

NCCN appreciates the opportunity to respond to the CMS Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates. We would welcome the opportunity to discuss our comments further and look forward to working together to ensure access to high quality, high value care for patients with cancer.

Sincerely,

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