September 25, 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


Dear Administrator Verma:

The National Comprehensive Cancer Network® (NCCN®) wishes to provide comments on the August 7, 2018 Centers for Medicare and Medicaid Services (CMS) guidance allowing Medicare Advantage plans to impose mandatory step therapy and other methods of prior authorization for Part B drugs beginning in 2019. NCCN believes that allowing the use of step therapy for Part B drugs without appropriate safeguards, such as the incorporation of clinical practice guidelines, would negatively impact the ability of patients to access, and providers to deliver, clinically-appropriate cancer care.

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 across the continuum of care. 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 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.

The NCCN Guidelines are transparent, continuously updated, available free of charge online for non-commercial use and through a multitude of health information technology vendors, and NCCN Guidelines and compendia products are utilized by commercial payers that represent more than 85 percent of covered lives in the United States.

CMS guidance to Medicare Advantage Plans Could Impact the Provider-Patient Relationship and Interfere with a Patient’s Cancer Treatment Plan; If Not Based on Proper Guidelines and Compendia

With the increasingly individualized nature of oncology care, clinicians and patients must choose a treatment that is most appropriate for the individual taking into account what matters most to the patient. Allowing Medicare Advantage plans to use step therapy for Part B drugs could threaten the provider-patient relationship, as well as restrict optimal evidence-based cancer treatment and care for Medicare beneficiaries. The utilization of step therapy for Part B oncologic drugs could limit the ability of providers to make the informed treatment decisions for the care of their patients, effectively taking clinical care decisions away from doctors and shared decision making from patients, thus negatively impacting the quality of care delivered. NCCN urges CMS to consider utilizing recognized guidelines and compendia, such as NCCN’s, as a safeguard to ensure that appropriate access to evidence-based cancer treatment is not compromised for patients with cancer.

Recently, Secretary Alex Azar met with representatives of specialty-physician and patient groups, including cancer organizations, to discuss the Trump Administration’s efforts to offer new tools for Medicare Advantage plans to negotiate lower drug prices for patients. We were encouraged to see that Secretary Azar expressed his openness in innovative solutions that may alleviate burdens for providers, and ultimately for patients, under new negotiation tools, such as step therapy.1 Moreover, in that same meeting, Azar encouraged physicians to work with Medicare Advantage plans to incorporate medical societies2 clinical pathways and preferred practice patterns into the step therapy processes.2 NCCN strongly supports the use of clinical pathways and preferred practice patterns to ensure access to appropriate therapies for patients. NCCN believes that the best way to ensure high-quality care and lower total drug spend in the Medicare program, is through the adoption of a policy that encourages or mandates the use of

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multi-disciplinary, specialty-developed, evidence-based guidelines in making treatment decisions. This occurs regularly in commercial payer settings and could occur in Medicare Advantage, fee for service Medicare, and in Medicaid.

Application of NCCN Guidelines by UnitedHealthcare Generated Significant Savings

One such mechanism to ensure high-quality medical care at lower cost was a successful demonstration of total and episodic cost of care reduction in the commercial marketplace. NCCN, UnitedHealthcare, and eviCore conducted a study across the state of Florida that focused on a key payment intervention – adherence to NCCN Guidelines and the NCCN Compendium- for on- and off-label anti-cancer therapy – in assisting physician decision making to make appropriate patient-centered decisions, among a choice of clinically appropriate drugs. Published in the Journal of Oncology Practice, this pilot demonstration found a 20% reduction in chemotherapy drug spending compared to drug spending trends across the country during that period. This represented a $5.3-million savings for the state of Florida. Given that this study found promising cost savings without comprising quality of care, this study is being replicated by several additional payers and specialty pharmacy providers. We believe the model is applicable to the Medicare Advantage beneficiary populations and holds promising possibilities for cost savings, as well as improved care outcomes without compromising beneficiaries’ access to drugs.

While NCCN is focused specifically on cancer and cancer-related treatment modalities such as diagnostics, imaging, radiation and surgery, these modalities are some of the most costly in the Medicare and Medicaid programs. A focus on real-time decision support through use of guidelines and compendia, affirmed by the physician and embedded into a utilization management tool or electronic medical record, could effectively reduce the number of denials and lower the total cost of drug-related treatments. Moreover, this model supports President Trump’s ideals of high-quality medical care at lower cost, while leaving the physician and patient responsible for the best treatment decisions.

Additionally, NCCN supports the American Cancer Society Cancer Action Network’s set of patient protections that should accompany step policy therapies and we encourage CMS to incorporate these recommendations moving forward. These protections include:

- Evidence-based treatment guidelines that avoid making patients use medically inappropriate therapies.

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• A simple, fast waiver processes that avoids treatment delays. Also, CMS should monitor exception requests to determine whether categories of drugs should be exempted from step therapy.
• Full transparency so Medicare beneficiaries who are shopping for plans can tell whether Part D plans use restrictive step therapy.

We appreciate Secretary Azar’s openness to solutions that may alleviate the burden that could be imposed on physicians by the new negotiation tools; however, NCCN, like other stakeholders, was disappointed that this decision was not implemented via a formal rulemaking process. NCCN encourages CMS to consider public comments throughout the implementation of this policy to ensure equal stakeholder involvement in solutions that drive patient-centered care.

NCCN appreciates the opportunity to provide feedback and solutions to address our shared concerns that patients, especially those battling cancer, are not impeded from making informed treatment choices that may have a negative impact the quality of care they receive. NCCN stresses the importance of utilizing specialty-developed, evidence-based guidelines as guardrails for any future step therapy implementation. This should be done in an administratively unobtrusive way and the impact of these policies on patient care should be closely tracked.

We would welcome the opportunity to discuss our comments further and to bring eviCore and UnitedHealthcare or other payers to meet with you as well. We look forward to working together to ensure access to high quality, high value care for patients with cancer.

Sincerely,

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