February 13, 2023

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4201-P
P.O. Box 8013
Baltimore, MD 21244

**Re: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (CMS-4201-P)**

Dear Administrator Brooks-LaSure:

On behalf of The US Oncology Network (The Network), which represents over 10,000 oncology physicians, nurses, clinicians and cancer care specialists nationwide, thank you for the opportunity to comment on the "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications" [CMS-4201-P] Proposed Rule.

The Network is one of the nation's largest and most innovative networks of community-based oncology physicians, treating more than 1.2 million cancer patients annually in more than 450 locations across 25 states. The Network unites over 1,400 like-minded physicians around a common vision of expanding patient access to the highest quality, state-of-the-art care close to home and at lower costs for patients and the health care system. We are committed to working with the Centers for Medicare & Medicaid Services (CMS) to enhance the delivery of cancer care and protect patient access to high-quality, affordable care in the most efficient manner.

The Network will focus our comments on Section 5 of the Proposed Rule, specifically the provision titled, "Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools."

As community-based providers of complex cancer care, we applaud CMS for recognizing the barriers to timely access to care created by increased use of prior authorization (PA) by Medicare Advantage (MA) plans. With the growth in the number of new cancer treatments available, cancer care has become both more complex and more tailored to the individual patient. Oncologists work closely with their patients to develop personalized treatment plans by evaluating each patient's medical history, the presence of comorbidities, potential drug interactions, type and stage of cancer, specific mutations present, and intent of therapy, in addition to other patient and/or disease-specific factors.

For cancer patients, access to timely and individualized care is paramount; however, the use of prior authorization continues to rise, burdening physicians and staff, increasing practice operating costs, and

delaying time-sensitive care for patients. A 2021 survey by the American Medical Association found that more than 93 percent of surveyed physicians reported care delays as a result of prior authorization, 34 percent reported prior authorizations lead to a serious adverse event and 82 percent reported that the burden associated with prior authorizations led to treatment abandonment.[1]

Prior authorization requirements interfere with the doctor-patient relationship by allowing a third-party to deny a treatment that has been prescribed based on a physician's assessment of clinical need. A patient may experience irreversible disease progression as they wait to receive the intended drug or treatment protocol initially prescribed by their oncologist. Often, prior authorization requirements only delay necessary treatment that is ultimately approved. A 2019 survey from the American Society for Radiation Oncology found that 93% of radiation oncologists nationwide said prior authorization delays patients from receiving life-saving treatment. The survey also found that the majority of prior authorization requests are initially approved and 62% of respondents said most denials are overturned on appeal.[2]

*Coverage Criteria for Basic Benefits*
In the Proposed Rule, CMS proposes to codify standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than Traditional Medicare. Specifically, CMS proposes that MA plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and Traditional Medicare statutes and regulations. CMS also proposes to codify that a MA plan cannot deny coverage of an item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies. When there is no coverage criteria in Medicare statute, regulation, NCD, or LCD, CMS proposes to allow MA plans to create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. In creating these internal policies, MA plans would have to post a public summary of the factors the MA plan considered during the development of internal coverage criteria used to make medical necessity determinations.

This proposal follows an April 2022 report released by the HHS Office of the Inspector General that found MA plans sometimes delayed or denied prior authorization and payment requests even though they met Medicare coverage rules. Often the denials used clinical criteria not contained in Medicare coverage rules. The Network supports CMS' proposal to inject much needed transparency and accountability into the use of PA in MA and the development of MA plans' internal coverage criteria.

CMS states that the use of clinical treatment guidelines that require another item or service to be furnished prior to receiving the requested item or service, would be prohibited under this proposal unless it is permitted by Medicare statute or regulation or by an NCD or LCD. However, CMS notes it is not proposing to change the current authority for MA plans to use step therapy policies for Part B drugs. The Network strongly encourages CMS to reconsider this position and reinstate the previous prohibition on step therapy for Part B drugs in MA plans. Like prior authorization requirements, step therapy protocols can delay time sensitive care and cause irreparable harm for cancer patients.

Also known as "fail first," step therapy forces patients to try a drug that is preferred by their insurance plan before they can proceed to the drug prescribed by their physician. As medicine becomes more and more tailored to the unique traits of individual patients, step therapy policies continue to force patients into a one-size-fits-all model of care that prioritizes potential cost saving over individualized treatment and patient health outcomes. Often, step therapy may require a patient to fail first on a drug that is more toxic, or that the provider knows is likely to be ineffective, or even one the patient has already tried and failed on while covered under a previous health plan.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5885220/
[2] ASTROPriorAuthorizationPhysician-SurveyBrief.pdf

In the Proposed Rule, CMS states that allowing step therapy for Part B drugs can "put MA organizations in a stronger position to negotiate lower pharmaceutical prices with drug manufacturers, reducing the cost sharing for the beneficiary." However, Network physicians have seen instances where insurers require patients to fail first on a more expensive brand drug before they can try a less expensive biosimilar. Further, step therapy policies are not clear or consistent across payers, including MA plans, causing needless confusion for both patients and providers. These burdensome policies divert critical time physicians could spend with patients and instead force them to dedicate their attention to a lengthy, bureaucratic, opaque appeals process. The Network believes providers are best suited to direct treatment to less expensive medications without compromising clinical efficacy.

A July 2022 analysis examined the use of step therapy for Part B drugs by four large Medicare Advantage insurers. The study found that of the top 20 physician-administered drugs, 10 were subject to step therapy by at least one insurer.[3] At the same time, step therapy is prohibited in Traditional Medicare. Patients enrolled in for-profit MA plans should have the same access to timely, personalized therapies as patients enrolled in traditional Medicare.

*Continuity of Care*

CMS proposes to require MA plans to make all approved prior authorizations valid for the duration of the entire approved prescribed or ordered course of treatment or service. The Network applauds this proposal and encourages CMS to finalize it. Non-medical switching, whereby a treatment is changed to an alternative therapy for non-clinical reasons, can negatively impact patient outcomes. These changes are driven by the patient's insurance plan and often aimed at reducing treatment costs but may actually increase net costs to the healthcare system due to higher administrative costs, treatment failure, and increased adverse events.[4]

Put simply, if a cancer patient is responding to a prescribed therapy, the patient should be allowed to stay on that therapy to finish the course of treatment. Requiring a cancer patient to switch to a new treatment when their current one is working is never appropriate. During the time it takes to stop a therapy, wait for the prior authorization to go through for the new therapy, and start a new therapy, a cancer can progress. Additionally, the patient may not respond as well to the new treatment or experience difficult side effects from a new treatment.

CMS further proposes that MA plans must have policies for using prior authorization that provide for a minimum 90-day transition period for any ongoing course(s) of treatment when a beneficiary has enrolled in an MA coordinated care plan after starting a course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider. This includes enrollees who are new to an MA coordinated care plan having either been enrolled in a different MA plan with the same or different parent organization, or an enrollee in Traditional Medicare and joining an MA coordinated care plan, and beneficiaries new to Medicare and enrolling in an MA coordinated care plan. The Network supports the requirement for plans to have a transition period for patients who switch to a new MA plan but cautions that the 90-day period is insufficient for patients with treatment plans that extend beyond 90 days. For example, metastatic patients should be able to remain on a treatment as long as the cancer is responding and patients with breast cancer receiving adjuvant therapy may also be on treatment for longer than 90 days. To complete an NCCN standard course of adjuvant therapy means patients receive surgery prior to starting chemotherapy, and can last up to one year. Neither should be required to switch to a new therapy simply because they switched insurance plans. We encourage CMS to make this clarification.

[3] https://www.ajmc.com/view/medicare-advantage-coverage-restrictions-for-the-costliest-physician-administered-drugs

[4] The non-medical switching of prescription medications - PubMed (nih.gov)

*Annual Review of Utilization Management Tools*
CMS proposes to require MA organizations to establish a Utilization Management (UM) committee to operate similar to a Pharmacy and Therapeutics, or P&T, committee. The UM committee would review UM, including PA, policies annually and keep current LCDs, NCDs, and other Traditional Medicare coverage policies. CMS proposes that the UM committee must be led by the MA plan's medical director and include a majority of members who are practicing physicians, one practicing physician who is independent and free of conflict relative to the MA organization and MA plan, one practicing physician who is an expert on care of elderly or disabled individuals, and members representing various clinical specialties. CMS solicits comment on whether the agency should include a requirement that, when the proposed UM committee reviews UM policies applicable to an item or service, the review must be conducted with the participation of at least one UM committee member who has expertise in the use or medical need for that specific item or service. The Network encourages CMS to require UM committee members be comprised of board-certified physicians in the applicable specialty.

*Additional Areas for Consideration and Comment: Gold Carding*
The Network appreciates CMS' recognition that "the use of gold carding programs could help alleviate the burden associated with prior authorization and that such programs could facilitate more efficient and timely delivery of health care services to enrollees." To this end, The Network supports The GOLD CARD Act, introduced by Congressman Michael Burgess, M.D. (TX-26), which would empower high-performing physicians to bypass PA requirements, helping patients get the treatment they need sooner and allowing physicians to spend more time with their patients. We supported similar legislation signed into law in Texas and encourage MA plans to implement gold carding programs.

Conclusion
On behalf of The US Oncology Network, thank you for the opportunity to provide our comments on Proposed Rule CMS-4201-P. We welcome the opportunity to discuss the issues outlined above and other critical issues impacting community cancer care with you and your staff. Should you have any questions, please contact Ben Jones, Vice President of Government Relations and Public Policy, at Ben.Jones@usoncology.com.

Sincerely,

Rhonda Isenschul

Vice President, Payer Relations