The National Association for Proton Therapy

February 15, 2023

VIA Electronic Submission to Regulations.gov

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: [CMS-4201-P] 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

Dear Administrator Brooks-LaSure:

On behalf of the National Association for Proton Therapy (NAPT), please accept the following comments in response to the Contract Year 2024 Medicare Advantage ("MA") Program Policy and Technical Changes Proposed Rule.

NAPT is a nonprofit organization of world-renowned cancer centers, a number of whom are National Cancer Institute (NCI) designated comprehensive cancer centers and National Comprehensive Care Network (NCCN) members.[1] NAPT's mission is to work collaboratively to: (i) educate and raise awareness of the clinical benefits of proton therapy among patients, providers, payers, policymakers, and other stakeholders, (ii) ensure patient choice and access to affordable proton therapy, and (iii) encourage cooperative research and innovation to advance the appropriate and cost-effective utilization of proton therapy for certain cancers.

NAPT offers comments regarding: (i) Medicare Advantage (MA) plans' use of utilization management (UM) and prior authorizations to delay and deny coverage and payment for covered services; and (ii) the use of MA Plan's internal criteria for evaluating coverage in the absence of a National Coverage Determination (NCD) or Local Coverage Determination (LCD).

I. Impact of Prior Authorization on Cancer Care

As background, NAPT members are spending an increasing amount of time on the authorization and appeal processes for cancer patients seeking advanced cancer treatments. NAPT members far too often encounter MA Plans that inappropriately use prior authorization procedures to deny or delay coverage for services otherwise covered under original Medicare. Although our members may succeed in appealing denials, the initial denials coupled with the material delays are adversely impacting appropriate access to critical cancer care. As a result, the use of prior authorization requirements limits appropriate beneficiary access and are, therefore, in conflict with CMS regulations and the Medicare Managed Care Manual. NAPT's concerns are shared by numerous other stakeholders and noticed by the Office of the Inspector General for the Department of Health and Human Services (HHS OIG) in its report that CMS also cited in this Proposed Rule.[2]

[1] Listing of members can be found on the NAPT website, please visit: http://www.proton-therapy.org.

[2] U.S Department of Health and Human Services, Office of the Inspector General, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" (Apr. 27, 2022), available at https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

The 2022 NAPT annual member survey found that MA plans denied 27% of prior authorization requests for items and services which would have otherwise been approved by original Medicare. This is more than double the rate of 13% reported in the OIG report. In addition, more than 50% of our members report of committing over 60 FTE hours per week on the prior authorization process. These types of policies also disrupt the patient-physician relationship, which should be focused on personalized, patient-centered care. Unfortunately, physicians and staff have less time to spend caring for patients and instead are required to fulfill requests for duplicate documentation or participate in peer-to-peer reviews with non-specialists who far too often are under resourced and inappropriately incentivized to perform an appropriate level of review. More importantly, this process increases distress for our members' patients when they are concerned about their health, finances and future wellness. While the denials may be ultimately overturned, there is an impact on a patient's mental well-being and risks associated with delaying care. Research demonstrates a 1.2% - 3.2% increased risk of death with each week of delay in starting cancer treatment.[3] All of these experiences and evidence serve to further reinforce that MA Plan's use of prior authorization policies unnecessarily delay and deny care to Medicare beneficiaries.

II. Support of Proposed Policy Changes on Utilization Management and Prior Authorization

As CMS highlighted in the Proposed Rule, particularly in the last few years, there has been more vocal feedback from stakeholders across the continuum that prior authorization and other utilization management tools have become a barrier to patients having access to medically appropriate clinical care. The aforementioned OIG report found that (a) "some prior authorization requests were denied by MA plans, even though the requested services met Medicare coverage guidelines" and (b) "prior authorization requests were inappropriately denied due to errors that were likely preventable through process or system changes by MA organizations." Given the on-going challenges with prior authorization, NAPT supports proposed policy changes that bring transparency and more definition to the PA process to ensure that beneficiaries have access to medically necessary and clinically appropriate care.

A. Compliance with Existing NCDs and LCDs

As articulated in the Proposed Rule, MA plans are not permitted to limit coverage through the adoption of policies or procedures that would deny coverage or payment where Medicare fee-for-service would cover or pay for the service for a beneficiary. These policies and procedures cannot be more restrictive than Medicare national coverage determinations (NCDs) or local coverage determinations (LCDs) by the Medicare Administrative Contractor (MAC) for the MA plan's service area. In practice, however, NAPT members frequently encounter prior authorization and payment processes from MA Plans that fail to align with coverage determinations made by applicable MACs. Our members encounter burdensome prior authorization requirements for cancer treatment that go well beyond the requirements of LCDs where established. This practice violates the above cited requirement as articulated in Chapter 4, Section 10.16 of the Medicare Managed Care Manual. Overall, patients treated by our members have had coverage delayed or denied through the prior authorization process where, if the patient were enrolled in original Medicare, his or her local MAC would have approved them for the treatment. ***Therefore, NAPT applauds CMS for codifying and clarifying these requirements as outlined in §422.101 and urges the Agency to finalize as proposed***.

B. Application of Internally Developed Clinical Criteria in Absence of NCD or LCD

In the absence of an NCD or an applicable LCD, currently, a MA plan is permitted to apply internally developed coverage criteria. In the Proposed Rule, CMS presents two critically important policy proposals specific to this flexibility. First, CMS proposes to limit the type of evidence – specifically widely used treatment guidelines and published clinical literature – that an MA plan may consider in the development of its criteria. Second, CMS proposes that MA plans would be required to provide a "publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to

[3] Khorana AA, Tullio K, Elson P, Pennell NA, Grobmyer SR, et al. (2019) Correction: Time to initial cancer treatment in the United States and association with survival over time: An observational study. PLOS ONE 14(4): e0215108. https://doi.org/10.1371/journal.pone.0215108.

make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination."[4] NAPT supports these proposed policies to promote greater transparency on the criteria that MA plans use in coverage determinations. However, ***NAPT believes that CMS should require MA plans to develop an open, transparent, well-informed and standardized public engagement process that it undertakes <u>when defining this criteria</u> rather than waiting until after the MA plan has finalized it. Furthermore, both providers and beneficiaries should be afforded the opportunity to appeal criteria that is arbitrary and capricious, e.g., are not supported by the evidence or standard of care.*** In doing so, CMS would further its stated goal that MA enrollees receive access to the same medically necessary care as one would under original Medicare.

C. Establishment of Utilization Management Committee

In this Proposed Rule, CMS also proposes to require MA plans to establish a Utilization Management Committee, led by the MA plan Medical Director. The intent of this committee would be to review utilization management, including prior authorization policies, annually and ensure consistency with existing traditional Medicare NCDs and LCDs, and other traditional Medicare coverage policies. CMS describes this proposed committee as similar to a Part D plan Pharmacy & Therapeutics (P&T) committee for policy development and formulary management. Historically, stakeholders have expressed concerns with the process and transparency of MA plan P&T committees. For example, MA plans do not regularly release minutes from P&T meetings in a timely manner, often released after the decisions in question have been made. In addition, these minutes when finally released often have insufficient detail. ***NAPT supports CMS' proposal but encourages CMS to address these concerns when finalizing this proposal by establishing clear process requirements (e.g., scheduled quarterly meetings) to ensure transparency with stakeholders***. ***Furthermore, NAPT respectfully requests that CMS consider specifically charging such committees with systematically reviewing appealed caseloads to determine, for example, whether MA plan operations are complying with the relevant requirements so as to not unduly burden provider, MA plan, and the Office of Medicare Hearings and Appeal (OMHA) resources through unnecessary appeals.*** Additionally, NAPT encourages meetings to be designed to allow industry partners to provide input.

A key responsibility of this UM committee would be the annual review of any UM policies, including PA policies and procedures, to ensure that these policies are consistent with the requirements as finalized as part of this rulemaking cycle. Further, in this proposal, no UM policies may be deployed by the MA plan on or after January 1, 2024 unless the policy has received a careful review and approval by the UM committee. ***NAPT supports this policy provided that the policies are not only reviewed but also updated as needed to reflect the latest clinical evidence***.

D. Review of Medical Necessity Decisions by Healthcare Professional with Expertise in Applicable Field of Medicine

An on-going challenge for providers, including NAPT members, is the review of submitted documentation in support of prior authorization requests. Current regulations at § 422.566(d) state that if the MA plan expects to issue a partial or fully adverse determination, it must be reviewed by "a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision." While coverage redeterminations must be reviewed by a physician with appropriate expertise in the applicable field of medicine, this requirement does not currently apply to the initial determination.

In this Proposed Rule, CMS proposes to modify this requirement by requiring that the physician or other appropriate health care professional conducting the review of the initial determination must have expertise in the field of medicine that is appropriate for the item or service being requested. This review must occur before the MA plan or applicable integrated plan issues an adverse organization determination decision. ***NAPT supports this request as it believes that this revision, linking the requisite expertise of the***

[4] 87 FR 79501.

reviewer to the specific service that is the subject of the organization's determination request, will address some concerns articulated by its members. However, NAPT believes that CMS should refine this proposed policy by requiring a specific specialty or subspecialty (e.g., radiation oncologist versus oncology more broadly) that is applicable for the item or service being requested.

E. Application of Prior Authorization Requirements Significantly Harm Health Equity within the MA Program

As CMS considers how to ensure that all MA enrollees receive the care they need, it is important to follow the Cancer Moonshot's lead which encourages underserved communities to have equitable access to high-quality cancer treatment options. Because MA plans have become more affordable and offer supplemental benefits, they disproportionally enroll low-income and minority Medicare beneficiaries, especially in "dual eligible" programs.[5] A recent study[6] found that non-Hispanic Black, Hispanic, and Asian patients were significantly more likely to have delays in initiation of radiotherapy compared to their non-Hispanic White counterparts. Another notable factor in the study was that Black patients with private insurance had longer delays than Black patients enrolled in Medicare. This data raises the troubling specter that prior authorization requirements may disproportionately affect minority patients, and most importantly, delay the treatment of their illnesses longer than their non-minority counterparts. It is particularly troublesome, as other studies have found that Black and Hispanic patients are more likely to present with advanced-stage cancer than their White counterparts, making it more important to promptly begin radiotherapy. This potential link causes significant harm to beneficiaries and to CMS's goal of health equity in the MA program.

In this Proposed Rule, CMS has proposed a number of policies to advance health equity across its programs including:

(1) Ensuring services are furnished in a culturally appropriate manner,
(2) Use of provider cultural and linguistic capabilities in provider directories,
(3) Develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy, and
(4) Requirement of plans to incorporate at least one program or policy to address health and healthcare disparities into its quality improvement (QI) program.

We commend these proposed policies by CMS but encourage CMS to ensure that it contemplates health equity and revises, as needed, these prior authorization policies. Lastly, CMS should also incorporate meaningful enforcement mechanisms should MA plans routinely deviate from CMS' requirements to ensure that utilization management and prior authorization requirements are given due attention.

* * *

NAPT has significant concerns with MA Plans' application of utilization management and prior authorization policies related to advanced cancer treatments such as proton therapy, as well as far too many MA Plans' application of commercial coverage guidelines. Many recommendations put forth by NAPT, and likely other stakeholders, are consistent with or mirror the provisions in the "Improving Seniors' Timely Access to Care Act" (HR 3173/S 3018). This legislation has broad and extensive bipartisan support not only in Congress but across the healthcare continuum with over 500 endorsing organizations representing patients, providers, the medical technology and biopharmaceutical industry, and several MA plans

NAPT appreciates the opportunity to submit these comments in response to the Proposed Rule and urges CMS to take action to ensure that MA beneficiaries have timely access to and receive clinically appropriate

[5] Study: Low-Income and Minority Populations Use Medicare Advantage Plans | Commonwealth Fund
[6] Hutten RJ, Weil CR, Gaffney DK, Kokeny K, Lloyd S, Rogers CR, Suneja G. Worsening Racial Disparities in Utilization of Intensity Modulated Radiation Therapy. Adv Radiat Oncol. 2022 Jan 20;7(3):100887. doi:10.1016/j.adro.2021.100887. PMID: 35360509; PMCID: PMC8960883.

cancer treatment. Please contact Jennifer Maggiore at jennifer@proton-therapy.org if you have any questions or would like to receive additional information.

Sincerely,

Jennifer Maggiore
Executive Director, NAPT