March 12, 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-0057-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

Dear Administrator Brooks-LaSure,

On behalf of the National Association for Proton Therapy (NAPT), please accept the following comments in response to the Proposed Rule for Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program.

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) adoption of revised prior authorization determination timelines; (ii) the increased data transparency on the use of prior authorization, and (iii) gold-carding for prior authorization requests.

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

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

often encounter plans, particularly Medicare Advantage 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. 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]

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. Specific Proposed Rule Recommendations

As discussed in the recent Medicare Advantage Contract Year Proposed Rule, many stakeholders across the continuum have expressed concerns about how prior authorization has become a barrier to patient access to medically appropriate clinical care.[4] This concern was further validated by the aforementioned OIG report where the OIG 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 strongly supports proposed policy changes that bring transparency and more definition to the PA process to ensure that beneficiaries have timely access to medically necessary and clinically appropriate care. It is important for CMS to

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[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.

[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.

[4] CMS-4201-P 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

understand that some plans contract with third party vendors for the utilization management (including prior authorization) function. NAPT urges CMS to specify that all finalized policy changes and clarifications for prior authorization requirements would also apply to contracted vendors.

A. Timeframes for Prior Authorization Determinations and Communications

Under the current Federal regulations, Medicare and Medicaid managed care plans must decide on a prior authorization request and send notice of its determination in no more than 14 calendar days under the standard timeframe. Expedited requests for prior authorization must be decided on and communicated by the plans within seventy-two hours. In this Proposed Rule, CMS does not propose to change the expedited timeframe but proposes to change the timeframe for a standard request to seven calendar days.

While NAPT supports efforts to ensure prior authorization requests are processed in a timely fashion, we remain concerned that these timelines are too long and the effective date of these policies (if finalized) is not until January 1, 2026. As captured in the AMA's prior authorization physician survey, there is a clear association between prior authorization requirements and treatment delays/abandonment, negative clinical outcomes, and even serious adverse events, including hospitalizations and patient death.[5] This is particularly concerning for expedited requests, where prior experiences indicate some expedited requests are immediately denied and sent to external review, thereby meeting the letter of the 72-hour deadline but failing to provide a meaningful clinical review within that timeline. We therefore urge CMS to adopt the prior authorization processing timelines outlined in the AMA's Prior Authorization Principles (that is, 24 hours for expedited prior authorizations and 48 hours for standard prior authorizations). Furthermore, we urge CMS to finalize these revised timelines effective January 1, 2024 rather than delaying the effective date for an additional two years in order to prevent patient harm associated with administrative delays in providing care.

B. Public Reporting of Prior Authorization Metrics

In order to increase transparency, CMS proposes to require impacted payers to publicly report prior authorization metrics on their websites, which would be compiled from multiple sources, on multiple measures and individuals, and compiled into aggregate data for reporting. Specifically, impacted payers would be required to report the following metrics by March 31, 2026 and annually thereafter:

- Items and services requiring prior authorization;
- Percentage of standard and expedited PA requests approved and requests denied, each reported in aggregate;
- Percentage of standard PA requests approved after appeal in aggregated;
- Percentage of PA requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services; and
- Average and median time that elapsed between the request submission and a plan determination for standard and expedited prior authorizations, each reported in aggregate.

NAPT strongly supports the collection and public reporting of impacted payers' prior authorization program metrics to increase transparency and support improvements in prior authorization processes.

[5] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

However, we recommend the following modifications to the proposal to ensure that the data is meaningful for providers and patients:

1. **Require the impacted payers to report the data in aggregate and, at a minimum, by category of items and services**. Disclosure on an aggregate basis will likely have limited utility to both providers and patients. Public reporting at the category of items and services level would enable patients to make more informed decisions when selecting a payer network based on their specific care needs and preferences. In addition, more detailed public reporting would better enable analysis of payer trends in prior authorization and the impact of CMS' other proposals over time.
2. **Set a specific deadline each year for the reporting of prior authorization metrics from the prior year**. As drafted, the policy proposal only imposes a date-specific deadline for the first year of public reporting, stating that after the initial report, "impacted payers must annually report certain aggregated prior authorization metrics from the previous year." This lack of specificity regarding the ongoing reporting cadence is likely to result in impacted payers reporting data at different times throughout the year, requiring patients to repeatedly check multiple data sources in an effort to track down the most up-to-date information from each payer.
3. **Establish requirements or guidelines for the reporting of PA metrics**. The policy proposal defers to impacted payers on the format for reports, only encouraging them to "consider readability and accessibility in preparing the data for viewing and comprehension." The lack of guidance on report formatting may result in wide variation across payers, requiring patients to learn and interpret each payer's format in order to compare data across payers and make decisions about their care.

C. Gold-carding for Prior Authorization Requests

In the Proposed Rule, CMS expressed interest in "gold-carding" programs and/or similar programs for providers that have a demonstrated and consistent pattern of compliance. The Agency seeks feedback from stakeholders on incorporating these types of programs in the future to reduce administrative burden and improve access to patients. A recent AMA survey of providers found that 88 percent of respondents believe PA processes generate "high or extremely high burden", and more than 8 in 10 providers indicated prior authorization issues sometimes, often, or always led to patients abandoning their treatment.[6] Concepts such as "gold-carding" programs may be one approach to recognizing and reducing burden on high-performing physicians who consistently request authorization for appropriate services. So long as the program criteria are reasonable, well informed, and transparent, and providers have equitable access (including appeal rights), NAPT supports the adoption of "gold-carding" or similar types of programs as a method to streamline and reduce burden associated with the use of prior authorization programs. NAPT believes that the transparent, well informed and equitable establishment of reasonable programs should not create significant additional costs to payers, as they already collect and analyze performance data for network placement and provider profiling programs and otherwise manage appeals in the normal course.

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[6] 2021 AMA Prior Authorization Survey (https://www.ama-assn.org/system/files/prior-authorization-survey.pdf).

NAPT has significant concerns with the application of prior authorization policies related to advanced cancer treatments such as proton therapy. The 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 patients have timely access to and receive clinically appropriate 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