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September 30, 2023

Dr. Elizabeth M. Jaffee, Chair President's Cancer Panel 9000 Rockville Pike Building 31, Room B2B37, MSC 2590 Bethesda, MD 20892

Dear Dr. Jaffee,

On behalf of the National Association for Proton Therapy (NAPT), thank you for the opportunity to share our initiatives on shortening patient delays to innovative cancer treatment and supporting access to proton therapy, an advanced type of radiotherapy, with the President's Cancer Panel. NAPT is an independent nonprofit organization founded in 1990 to educate and increase awareness about the clinical benefits of proton therapy. Its members¹ include 47 of the nation's leading cancer centers, many of which are NCI-designated comprehensive cancer centers and NCCN members. The mission of NAPT is to work collaboratively to raise public awareness of proton therapy, ensure patient choice and access to affordable treatment, and encourage cooperative research and innovation to advance proton therapy's appropriate and cost-effective utilization.

Proton therapy is a radiation treatment modality that has the proven ability to reduce side effects for patients by limiting the amount of normal tissue exposed to radiation. Unlike conventional x-ray radiation, which has both entrance and exit doses, proton therapy delivers radiation to the target, with little to no radiation extending beyond the target. In addition to these acute and late toxicity benefits of proton therapy over conventional radiation therapy, proton beam therapy has been shown across multiple disease sites to improve overall survival, either by reducing life-threatening toxicities, being more biologically potent at tumor killing, or allowing for more targeted and escalated doses of irradiation to be delivered directly to the tumor. Over the years, there has been substantial evidence-based research demonstrating the effectiveness of proton beam therapy in treating various

<sup>&</sup>lt;sup>1</sup> Find A Proton Center - National Association for Proton Therapy (proton-therapy.org)



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malignancies, leading to its acceptance as a critical component of comprehensive cancer care for certain types of cancer.

Proton therapy, while a proven and life-saving cancer treatment, remains inaccessible to many patients whose physicians have recommended it for certain types of cancer. Restrictive insurance guidelines and a burdensome prior authorization process create barriers for cancer patients and often lead to negative patient outcomes. The lack of insurance coverage limits the number of patients participating in clinical trials, hindering the ability to generate further evidence supporting the value of proton therapy. A 2018 survey by the American Society for Radiation Oncology (ASTRO) found that 93% of radiation oncologists had encountered treatment delays due to prior authorizations, with 31% reporting delays lasting more than five days – equivalent to a full week of standard radiation treatment. Through our annual member survey, we found that Medicare Advantage Organizations denied 27% of claims that met Medicare coverage rules, two times the rate of denials reported by the OIG.

Regrettably, the prior authorization procedures frequently restrict the access of underserved communities to top-tier cancer treatment alternatives and their chance to engage in clinical trials. 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<sup>2</sup>. A recent study<sup>3</sup> found that non-Hispanic Black, Hispanic, and Asian patients were significantly more likely to have delays in the 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 and increased diversity in cancer clinical trials.

<sup>&</sup>lt;sup>3</sup> Worsening Racial Disparities in Utilization of Intensity Modulated Radiation Therapy - PubMed (nih.gov)







<sup>&</sup>lt;sup>2</sup> Study: Low-Income and Minority Populations Use Medicare Advantage Plans | Commonwealth Fund



NAPT is working with our member centers and has joined other stakeholders as members of the Regulatory Relief Coalition to reduce the impact of prior authorization on cancer patients' access to proton therapy. NAPT applauds CMS's efforts to address Medicare Advantage Prior Auth processes in their two proposed rules in 2023 and we eagerly anticipate the finalization of these rules. NAPT's comment letter<sup>4</sup> to CMS details the challenges providers experience when delivering care to patients. Clinical research is a critical piece to advancing cancer innovation. The prior authorization process of Medicare and Medicaid Advantage plans and commercial insurers often restrict cancer patients' access to clinical trials for proton therapy, hindering the development of evidence supporting radiation oncology innovation. In addition, there are variations in coverage guidelines from commercial insurers who manage Medicare and Medicaid managed care plans which often leads to disparities in access.

To reduce disparities and increase access to proton therapy and other advanced cancer treatments, organizations like NAPT need support in addressing the burdensome prior authorization processes for Medicare and Medicaid beneficiaries and patients with commercial insurance. We welcome the opportunity to continue to support the goals of the Cancer Moonshot and address the challenges of access to innovative cancer treatments. Please contact me at <a href="mailto:jennifer@proton-therapy.org">jennifer@proton-therapy.org</a> if you have questions or would like additional information.

Sincerely,

Jennifer Maggiore Executive Director

National Association for Proton Therapy

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<sup>&</sup>lt;sup>4</sup> MA-Technical-Rule-Comment-Letter-from-NAPT.pdf (proton-therapy.org)