

UMass Memorial Health Care, Inc.# UMMH -25021208 – HE
Questions #2

1. Regarding Factor 1 (Need), to better understand the number of patients who may be eligible for Proton Beam Therapy we are looking for a more accurate estimate of patients who would require Proton Beam Therapy for re-irradiation treatment (not using the Horizon estimates). Please provide additional data, where possible, to identify these patients.

RESPONSE:

Re-treatment with Radiation Therapy: Historical Context and Research

The need for re-treatment with radiation therapy is a growing challenge for oncology patients across the Commonwealth and beyond. As cancer incidence increases and society ages, more patients are surviving their initial malignancy, only to later face recurrence or a second unanticipated cancer event.

Specifically, the National Association for Proton Therapy reported that in 2024, nearly 15% of the 17,000 patients utilizing proton therapy were undergoing re-treatment, marking a >15% increase from the number of patients undergoing re-treatment in 2022. This has created a significant, clinically meaningful problem in modern radiation therapy while also demonstrating the urgent need for access to effective modalities for re-treatment.

A 2023 international survey of 371 radiation oncologists (Willmann et al., *Radiother Oncol* 2023;189:109947) confirmed the growing demand for re-treatment with radiation therapy across disease sites such as central nervous system, head and neck, thoracic, breast, abdominal, pelvic, and extremity malignancies. Nearly all respondents reported re-treating patients for local failures or isolated metastatic disease. Disease-specific studies and reviews (*Lancet Oncol* 2022;23:e469-78) consistently demonstrate that re-treatment is feasible and clinically meaningful across these areas.

Why Proton Therapy is Critical for Re-treatment

Radiation oncologists strive to deliver targeted treatment that spares normal tissue. When a patient is undergoing re-treatment, there are limited options with conventional photon therapy because it inevitably delivers additional radiation to healthy tissue. However, proton therapy offers a superior alternative by significantly reducing unnecessary radiation exposure to normal tissue¹. This precision makes proton therapy indispensable for re-treatment.

For head and neck cancers, for example, patients treated with protons experienced reduced feeding tube dependency and, in some studies, improved overall survival². For recurrent

¹ E.G.C. Troost, K.C.J. Wink, E. Roelofs, C.B. Simone 2nd, S. Makocki, S. Löck, et al. Photons or protons for reirradiation in (non-)small cell lung cancer: results of the multicentric ROCOCO in silico study *Br J Radiol*, 93 (2020), Article 20190879

² Chang C, Lin K, Chen W, et al Comparing the oncologic outcomes of proton therapy and intensity modulated radiation therapy for head and neck squamous cell carcinoma *Radiotherapy and Oncol* 2024 190 109971

UMass Memorial Health Care, Inc.# UMMH -25021208 – HE Questions #2

breast cancer, proton therapy demonstrated better dosimetry and outcomes compared to volume-modulated arc therapy³.

Recent national data reinforce both the clinical necessity of proton therapy and the urgent need to expand access. In a comprehensive analysis of 162,506 patients with central nervous system (CNS) tumors using the National Cancer Database, Amin et al. (2025) found that proton therapy was associated with a 33% reduction in the risk of death compared to photon radiation (HR: 0.67; 95% CI: 0.64–0.71; $p < 0.001$). This survival benefit extended across key subgroups, including those undergoing surgery (HR: 0.76) and those who did not (HR: 0.61), as well as multiple histologies, such as astrocytoma and glioblastoma.

Yet, despite this clear advantage, only 3.4% of CNS tumor patients in the cohort received proton therapy, highlighting a stark disparity between evidence-based need and real-world access. Moreover, the study identified significant socioeconomic barriers: patients with Medicare, Medicaid, or no insurance, as well as those from lower-income or less-educated communities, were significantly less likely to receive proton therapy. These findings underscore that without additional proton capacity in regions like Central Massachusetts, vulnerable populations—particularly publicly insured and rural patients—will remain disproportionately excluded from this life-extending therapy.

Real-World Examples of Patients Lacking Access

As documented in previously shared materials, capacity constraints limit existing patients' ability to seek proton therapy treatment in New England. According to data provided by Dana-Farber Cancer Institute (DFCI), local patients have traveled to states such as New York, New Jersey, Pennsylvania, or Florida to receive proton therapy in a timely manner because of insufficient local availability. In Massachusetts, DFCI also estimates that only a small percentage of the roughly 5,500 eligible patients they treat ultimately receive proton therapy.

At UMass Memorial Health, we see this unfold with our own patients, illustrating an access gap that the proposed facility will address. Below, please find a sampling of real stories of UMMH patients who could have benefited from access to proton therapy treatment.

- [REDACTED] patient with recurrent Wilms tumor requiring re-treatment. [REDACTED] re-treated with photons at our Fitchburg facility. [REDACTED] would have greatly benefited from proton therapy.
- [REDACTED] patient with recurrent Hodgkin lymphoma required treatment with photons in Fitchburg. [REDACTED] would have had significant reduction in swallowing sequelae with proton therapy.
- A [REDACTED] treated in Worcester for sphenoid ridge meningioma, re-treatment places chiasm at risk, would have benefited from proton therapy.

³ Cho J, McCormick B, Park P et al Comparative evaluation of proton therapy and volume modulated arc therapy for brachial plexus sparing in comprehensive reirradiation of high-risk recurrent breast cancer
Advances in Radiation Oncology 2024 9 2 101355

UMass Memorial Health Care, Inc.# UMMH -25021208 – HE Questions #2

- A [REDACTED] with recurrent glioma, currently on treatment in Fitchburg with photons who would benefit from proton therapy.

Re-treatment Patient Population in UMMH Service Area

Re-treatment is not documented in formal diagnoses as a separate clinical code. However, according to peer-reviewed literature and methodologies accepted by the oncological community⁴, it is estimated that re-treatment cases constitute 5-10% of all radiation courses in contemporary practice. Applying a conservative estimate of 8% to UMMH's proton-eligible patient volume, approximately 123 of Group 2 patients are likely to receive re-treatment. When combined with the 136 previously reported Group 1 patients in UMMH's service area, there is an estimated 259 patient cases where proton therapy would be considered the safest treatment modality. This patient volume alone could constitute 86.2% of UMMH's projected annual proton beam capacity.

Support from Massachusetts Radiation Oncology Community

The Massachusetts radiation oncology community has offered their full support for the proton project and the need to have an additional resource available to patients for re-treatment. Support letters have been written and formally submitted to the record by colleagues at Cape Cod Healthcare, Baystate Health, and DFCI. Additional letters in favor of this project citing patient need and convenience of location have been sent to Dr. Thomas J. FitzGerald, Professor & Chair, Department of Radiation Oncology, UMass Memorial Medical Center, from clinicians practicing across the state, including at Tufts Medical Center, Boston Medical Center, Holy Family/Lawrence General Hospital, Lahey Health, Dartmouth Hitchcock Medical Center, and Berkshire Medical Center. Each of these organizations/future referral sources recognizes the importance of proton therapy and the need for an additional center to

⁴ Nielsen, M. et al. (no date) *A comprehensive national audit of radiotherapy retreatment numbers, sites and indications*, *Acta Oncologica*. Available at: <https://medicaljournalssweden.se/actaoncologica/article/view/43825> (Accessed: 05 August 2025).

UMass Memorial Health Care, Inc.# UMMH -25021208 – HE
Questions #2

be operational in Marlborough, which is a highly accessible location for their respective patient populations. The formal comments are provided as an attachment to this document.

We anticipate that there will be more re-treatment patients who will be referred to our proton therapy center by other radiation oncology providers in Massachusetts than our initial projections indicate.

Closing

With the changing cancer landscape, proton therapy is an essential component of modern radiation oncology. We are prepared to provide this vital service to patients across the Commonwealth and beyond.

UMass Memorial Health Care, Inc.# UMMH -25021208 – HE
Questions #2

2. Also regarding Factor 1 (Need), Using UMMMC records, estimate the number of UMMMC patients receiving re-irradiation in CY24 who would have met criteria for re-irradiation with Proton Beam Therapy as defined in ASTRO Model Policy group 1 (where cumulative critical structure dose would exceed tolerance dose). It is acceptable to do this through chart review of a random sample of 100 charts of patients who received radiation. Please exclude cases already accounted for by other group 1 indications.

RESPONSE: In accordance with the request, UMass Memorial Health (UMMH) engaged a Radiation Oncologist to perform a random sample chart review of FY24 patients that fell within the Astro Group 1 and Group 2 patient panel to estimate the number of patients that would meet re-irradiation criteria for Proton Beam Therapy.

Due to the limited time to perform this review, UMMH was able to perform a sample chart review on only 218 of the total 1,669 combined Group 1 and Group 2 patient panel that was identified in **Exhibit D** of the DoN application. The chart review found that of the 68 patients sampled in Group 1, 10 of the patients (or 14.7%) met re-irradiation criteria. In Group 2, the chart review identified that 14 out of 150 patients sampled (9.3%) met re-irradiation treatment criteria. The combined Group 1 and 2 chart review suggests that the estimated percentage of UMMH patients that would meet re-irradiation criteria is 11% (24 out of 218) which falls within the range that other studies have identified as a normal re-irradiation rate.

Utilizing the results from physician chart review in combination with the UMMH FY22 and FY24 patient panel results, UMMH estimates that the total number of patients who would qualify for Proton Therapy ranges between 279 to 290 patients, as presented in the chart below. UMMH arrived at this range by conducting the following two steps. First, we estimated the Group 2 re-irradiation patients by multiplying the Group 2 patient panel (FY22: 1,394 patients and FY24: 1,533 patients) by 9.3%, as indicated in the chart review for Group 2 re-irradiation patients. Based on this calculation, we estimated that the Group 2 patient count is somewhere between 130 and 140 patients. For the second step, we added the estimated Group 2 re-irradiation patient count to the Group 1 patient panel count of 136 to 160 (FY24 and FY22, respectively).

It is worth noting that the FY22 and FY24 Group 1 patient panel count does include re-irradiation patients.

UMass Memorial Health Care, Inc.# UMMH -25021208 – HE
Questions #2

	Model 1: FY24 Patient Panel Results	Model 2: FY22 Patient Panel Results
Group 2 sample chart review results:		
Reirradiation Patient Count	14	14
Patient Sample Size	150	150
Reirradiation %	9.3%	9.3%
Group 2 Patient Panel Count	1,533	1,394
Grp 2 Reirradiation Est. Patients	143	130
Group 1 Patient Panel*	136	160
Est. Proton Patients (Lines 6 and 7)	279	290

* Includes both re-irradiation and non-re-irradiation patients

UMass Memorial Health Care, Inc.# UMMH -25021208 – HE
Questions #2

3. Regarding Factor 4 (Financial Feasibility) and in light of recent media reports of current and predicted UMMMC financial shortfalls, please provide the Department with an update on your financial status and how these cuts will impact the Proposed Project. (An update of the CPA report or letter from the CPA that explains the impact may be necessary if there is a variance of over 10% of revenues and expenses.) If the proposed PBT acquisition is no longer financially viable, please provide an explanation of how you will identify resources to proceed with the proposed project or alter the submission to match financial feasibility. Further, please explain whether acquiring the PBT service will draw resources away from other essential services and potentially compromise those programs, including compliance with the terms and conditions of previously issued DoNs.

RESPONSE: In its most recent public financial release for the quarter ended June 30, 2025, UMass Memorial Health (UMMH) reported a loss of \$1Million. This is a significant improvement compared to the first and second quarters, where we reported losses of \$59M and \$28M, respectively. These earlier losses included significant costs associated with opening the 72 new inpatient beds in the North Pavilion in January and integrating Milford Regional Medical Center into the system on October 1.

Throughout FY25, UMMH has continued to make capital investments in its operations and infrastructure while maintaining sufficient cash reserves for approved capital projects, including Proton Therapy, Nashoba Satellite Emergency Facility, and the Marlborough Emergency Department expansion. We firmly believe that the financial projections provided to BDO for the Proton Therapy project remain unchanged, as does the community benefit for the residents of Central and Western Massachusetts. Providing Proton Therapy at Marlboro will address a growing disparity and clinical need for patients unable to access cancer treatment that will improve survival and health outcomes.

Like other healthcare systems in Massachusetts, UMMH continuously monitors current and projected market conditions, along with the financial, operational, and quality performance of its various programs and services. This ongoing review process may sometimes necessitate modifications to meet patient needs and ensure the long-term financial wellbeing of the system, all while complying with the terms and conditions of previously issued DoNs. UMMH must provide a balanced set of programs for our unique patient payer population to operate a sustainable, lower cost academic safety net health care system that keeps patients local for their health care.