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

*Please Respond **by June 4th, 2025** at mailto:DPH.DON@State.MA.US*

While you may submit each answer as available, please

- List question number and question for each answer you provide;
- Submit responses as a separate word document, using the above application title and number as a running header and page numbers in the footer;
- When providing the answer to the final question, submit all questions and answers in one final document;
- Submit responses in WORD or EXCEL; include a table in data format (NOT pdf or picture) with the response.
- When providing a table of data, provide a narrative explaining the trends or significance of that information (such as what reason for the year over year changes are attributed to and how it relates to information already provided.)

QUESTION

1. What is the daily monthly and annual capacity of the Proton Beam unit you intend to acquire: provide your calculations including the average treatment time per patient, hours of operation, turnaround time etc. number of days per week, etc.

RESPONSE

After an initial ramp-up in Yr. 1, UMass Memorial Health (UMMH) has projected a daily capacity of 30 treatments, monthly capacity of 600 treatments and annual capacity of 7,200 treatments for the proton therapy center at Marlborough. UMMH plans to operate the new proton therapy center 14 hours per day, Monday through Friday (or 250 days per year). Initial patient treatment times during Yr. 1, including both treatment and turnaround, are projected at 30 minutes (resulting in 290 patients per year), with anticipated optimization to 25 minutes by Yr. 2 (resulting in 300 patients per year) as the team refines workflows and maximizes efficiency at the proton therapy unit. Hours of operation for the proton therapy center have been developed based on standard patient care hours and to allow necessary time for machine maintenance and quality assurance.

	Yr 1	Yr 2	Yr 3
Patient Volume (New Starts)	180	300	300
Radiation Treatments	4,320	7,200	7,200
Est. Avg Treatments per Pt	24	24	24
Hours per Day	14	14	14
Days in Year	250	250	250
Mins per Treatment	30	25	25
Total Est. Mins	129,600	180,000	180,000

QUESTION

2. **Exhibit D and page 12**, please explain further what the CED paradigm is. Do you expect to use the Unit for clinical trials? Do You have any estimation of the number of cases in group 2, based on the clinical diagnosis, that might meet over the next three to five years meet the "criteria for coverage". Does the "criteria for coverage" refer to coverage by insurance? Would that mean those patients would then move to Group 1.

RESPONSE

CED Paradigm

The Coverage with Evidence Development (CED) paradigm is a CMS policy that enables Medicare to provide coverage for promising medical services and technologies - such as proton therapy - in defined clinical scenarios, and to collect data to support the evidence base for the innovative service or technology through clinical trials or registries.

Specifically, in the context of this ASTRO Model Policy, the CED paradigm applies to "Group 2" indications: disease sites or patient populations where coverage decisions are guided by individualized clinical criteria, and where prospective data collection can contribute to the ongoing evaluation of treatment value. Under CED, radiation therapy with proton therapy is covered if the patient is enrolled in either:

- An Institutional Review Board (IRB)-approved clinical trial, or

- A multi-institutional registry that adheres to Medicare's CED requirements.

The purpose of the CED paradigm is to support the utilization and continued research of innovative services and technologies while providing access to cutting edge care and Medicare coverage for patients, such as patients treated with proton therapy.

Clinical Trials

UMass Memorial Health has extensive experience leading and participating in national clinical trials and registries that collect evidence of effectiveness.

Dr. TJ FitzGerald, Chair of Radiation Oncology at UMass Memorial Health, oversees the credentialing of all proton therapy centers participating in national research through his responsibilities with the National Institutes of Health (NIH) and the Imaging and Radiation Oncology Core (IROC). As a result of Dr. Fitzgerald's role with NIH and IROC, UMMH is particularly well-positioned to actively participate in all national clinical trials involving proton therapy. In addition, UMMH and Dr. Fitzgerald plan to launch investigator-initiated trials for UMMH's patient panel that will focus primarily on a comparison of patient outcomes observed for patients treated with proton therapy and patient outcomes observed for patients treated with photon therapy. The Proton Therapy Center at Marlborough will enable UMMH to engage in further research of

both the comparative clinical effectiveness of proton therapy and the downstream cost savings of proton therapy that result from such superior clinical effectiveness.

Criteria for Coverage

The term "criteria for coverage" refers to the requirements for insurance coverage for proton therapy. The ASTRO Model Policy[1] outlines the clinical and technical criteria insurance payers should consider for proton therapy to be medically necessary and therefore a covered service that is reimbursable. These criteria for coverage include clinical scenarios (e.g., proximity to critical body organs and areas, re-irradiation cases, genetic risk factors) that justify the use of proton therapy over conventional photon therapy from a payer's perspective.

The ASTRO Model Policy divides indications for proton therapy into:

- Group 1: Conditions where proton therapy is considered medically necessary, meeting established coverage criteria.

- Group 2: Conditions suitable for Coverage with Evidence Development (CED)—i.e., insurance may cover proton therapy if the patient is enrolled in a qualifying registry or clinical trial.

Meeting Group 2 criteria does not transfer patients into Group 1; rather, it qualifies these patients to have insurance coverage for proton therapy under Group 2 through documented superiority of proton therapy in sparing organs-at-risk (OARs) or participation in a qualifying registry or clinical trial.

Group 2 Estimated Cases in Worcester County Potentially Suitable for Proton Therapy

The following estimates provide a policy-aligned overview of Group 2 proton therapy coverage and eligibility projections in Worcester County, Massachusetts, from 2025 to 2030. It reflects payer coverage policies and addresses the role of the CED paradigm.

54.9% of UMass Memorial Health's proton payor mix is anticipated to be covered by Medicare and many commercial payers utilize Medicare policies to determine their coverage requirements. For this reason, it is necessary and appropriate to look to Medicare policies regarding proton therapy.

Medicare follows Local Coverage Determination (LCD) L35075, a policy that is closely aligned with the ASTRO Model Policy. Group 2 coverage is allowed when clinical documentation observes at least one of the following indications:

- Photon therapy exceeds organs-at-risk (OAR) dose constraints

- The target is adjacent to critical structures (i.e., the cancer is next to a critical body organ or area)

- The patient requires re-irradiation (i.e., the patient has already received radiation therapy and requires additional radiation therapy)

- Dose-volume histogram (DVH) comparison supports proton use over photon use.

Group 2 cancers explicitly mentioned in the LCD include prostate, breast, liver, lung, pancreatic, pelvic, and head & neck cancers. The following indications are covered under LCD L35075 with documentation.

ASTRO Category	Indications	Medicare (L35075)
Head & Neck	Salivary glands, mucosal melanoma, ipsilateral fields	✅
Breast	IMN+, bilateral, high cardiac dose	✅
Thoracic	Early or advanced NSCLC	✅
Abdominal	Pancreatic, adrenal, liver lesions	✅
Genitourinary	Prostate (non-metastatic)	✅
Pelvic	Rectal, cervical, bladder	✅

Coverage Symbols:
✅ = Covered with documentation (e.g., DVH showing OAR sparing)

Commercial insurance coverage of Group 2 proton therapy cases will be determined on an individual patient basis but again, commercial payers often consider Medicare coverage policies in determining their own coverage policies.

Based on State Cancer Profiles incidence rates for Massachusetts (2017–2021), UMMH applied the Dutch model-based proton therapy planning framework, a European standard for estimating patient subgroups that benefit most from proton therapy using Normal Tissue Complication Probability (NTCP) modeling, to derive local projections for the total number of Group 2 patients that may be eligible for insurance coverage for proton therapy. This model complements U.S. guidelines (also see Appendix).

Table of Estimated Group 2 Annual Eligible Cases by Cancer Type

Cancer Type	Incidence (per 100,000)	Annual Cases	% Eligible (Dutch Model)	Annual Eligible Cases	Projected 3 Year Case Total	Projected 5 Year Case Total
Prostate	116.3	~645	10%	~65	~194	~323
Breast	132.2	~710	5%	~36	~107	~178
Lung & Bronchus	62.3	~678	15%	~102	~305	~509
Pancreas	14.6	~156	10%	~16	~47	~78
Liver & Bile Duct	9.2	~103	10%	~10	~31	~52
Oral Cavity and Pharynx (Head and Neck)	13.2	~143	25%	~36	~107	~179
Bladder (Pelvic)	22.6	~239	10%	~24	~72	~120
		Total		~287	~862	~1,436

Population Base: ~862,111 | Data Source: Massachusetts Cancer Registry (2017–2021) Note: This table does not include re-irradiation as noted in the Dutch Model (25% eligible)

Under this framework and aligned with the CED paradigm, patients with Group 2 cancers may receive proton therapy when individualized clinical documentation, such as dose-volume histogram (DVH) analysis, demonstrates a potential benefit in sparing organs-at-risk, or when enrolled in an approved clinical trial or registry contributing to real-world outcomes research.

While the table above is not an exhaustive list of Group 2 cancer types, UMMH estimates approximately 862–1,436 Group 2 patients in Worcester County may be eligible for insurance coverage for proton therapy treatment over the next three to five years.

Ongoing clinical research and outcomes tracking are expected to further support the value of proton therapy in select patient populations, potentially broadening coverage as payers adopt criteria-based models informed by real-world evidence. As this body of evidence grows, UMMH anticipates that additional diagnoses currently classified under ASTRO Group 2 will become eligible for reclassification into Group 1.

References

- LCD L35075 – Proton Beam Therapy (Medicare)[1]

- ASTRO Model Policy for Proton Therapy (2023)[2]

- Massachusetts Cancer Registry – Incidence Data (2017–2021)[3]

- Dutch Model - Horizon Scanning Report "Proton Therapy Indications: Final Report and Policy Advice." 2009.[4]

- Dutch Expert Panel. "Model-based Clinical Indication for Proton Therapy - Update Report." 2016.[5]

Appendix: Dutch Model-Based Eligibility Forecast

The Dutch proton therapy planning model is a widely referenced benchmark for estimating the clinical appropriateness of proton therapy. Originally developed by the Dutch Health Council and refined in the 2016 Update Report, this model uses Normal Tissue Complication Probability (NTCP) calculations to identify patient subgroups who may benefit from proton therapy, even when the therapy is not routinely indicated.

Key elements include:

- **Model-based approach**: Patients are selected based on NTCP modeling comparing protons to photons.

- **Group 2 equivalency**: The "model-based indication" closely mirrors ASTRO's Group 2 definition.

- **Utilization estimates**: In 2016, the Dutch model projected that 14% to 15% of all radiotherapy patients could be eligible for proton therapy under model-based criteria.

Estimated eligibility percentages derived from the Dutch model are:

- Breast: 5%
- Prostate: 10%
- Lung: 15%
- Head & Neck: 25–70% depending on site
- Abdominal (e.g. pancreas, liver): 10–15%
- Pelvic (e.g. rectum, bladder): 10–15%

QUESTION

3.   **Exhibit F and page 13** - please explain further where the estimation that 15% of Radiation Therapy patients was derived from. Is that from the ACS or from UMMMC. Has it been peer reviewed, and has the model been tested in any region? Similarly, how was the 37% future increase derived.

RESPONSE

Calculation of 15%

UMMH relied on two different, publicly available data sources to calculate the total estimated number of proton patients that would benefit from Proton Therapy (PT) both from a statewide and UMMH total service area perspective.

UMMH first used American Cancer Society (ACS) data to estimate the total number of new cancer patients per year by tumor type based on statewide and UMMH total service area data derived from population estimates produced by the UMass Donahue Institute.

Once the total number of new cancer patients by tumor type was estimated, UMMH referenced a Dutch Model - Horizon Scanning Report[6] (Horizon Report) to calculate the estimated total number of radiation and proton therapy patients from the identified total number of new cancer patients per year. Please note, the Horizon Report defines its estimated percentage of patients by tumor site as cancer patients "for whom proton therapy may be indicated with the aim to reduce the risk of side effect," as illustrated in table 6.4 of the report.

Based on the percentages of proton therapy by tumor type, in conjunction with ACS estimated new cancer rates, UMMH was able to determine that 743 patients residing in UMMH's Total Service Area (TSA) or 15% of new cancer patients receiving radiation therapy. Please refer to Exhibit F Page 5 of the DoN Application which provides the details used in the calculations.

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[1] "LCD - Proton Beam Therapy (L35075)." *Cms.gov*, 2019, www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35075&ver=34&bc=0. Accessed 10 June 2025.

[2] *Model Policies PROTON BEAM THERAPY (PBT)*. 2023

[3] "State Cancer Profiles > Incidence Rates Table." *Statecancerprofiles.cancer.gov*, statecancerprofiles.cancer.gov/incidencerates/index.php.

[4] Knottnerus, Professor J. A. *Proton Radiotherapy Horizon Scanning Report*. 14 Dec. 2009, www.healthcouncil.nl/binaries/healthcouncil/documenten/advisory-reports/2009/12/11/proton-radiotherapy/advisory-report-proton-radiotherapy.pdf. Accessed 4 June 2025.

[5] The Quest for Evidence for Proton Therapy: Model-Based Approach and Precision Medicine
Widder, Joachim et al. International Journal of Radiation Oncology, Biology, Physics, Volume 95, Issue 1, 30 – 36.

[6] Knottnerus, Professor J. A. *Proton Radiotherapy Horizon Scanning Report*. 14 Dec. 2009, www.healthcouncil.nl/binaries/healthcouncil/documenten/advisory-reports/2009/12/11/proton-radiotherapy/advisory-report-proton-radiotherapy.pdf. Accessed 4 June 2025.

The estimate that 15% of total radiation therapy patients would clinically benefit from proton therapy has been peer reviewed.

A historical study conducted in Sweden[7] (Glimelius, et al., Acta Oncologica, 2005) found that approximately 14–15% of all radiation therapy patients annually would experience significant clinical gain from proton therapy based on tumor incidence, radiation utilization, and dose-response relations. The publication, *Acta Oncologica,* is a peer-reviewed academic journal that leverages systematic literature reviews and expert panel consensus. This report was cited by Danbury Proton in its approved Certification of Need [8] application to the State of Connecticut's Office of Health Strategy, demonstrating that other health care providers are using the 15% of total radiation therapy patients estimate in their calculations to identify patient need.

Another peer-reviewed and widely cited study, "Global democratisation of proton radiotherapy," in *The Lancet Oncology*[9] concluded that conservative global estimates suggest proton therapy could benefit 15–50% of radiation therapy patients.

These are just two of many studies that suggest proton therapy would prove clinically beneficial for 15% of total radiation patients.

Referenced Studies:

1. **Dutch Model – Horizon Scanning Report[10] -** *National report establishing proton therapy potential at around 15% of radiotherapy patients.*

2. **Dutch NTCP Model[11] -** *An update on the capacity needed for proton therapy in the Netherlands, estimating around 14–15% of radiotherapy patients benefiting significantly based on model-based (NTCP) criteria.*

3. **Italian Hadron Therapy Assessment[12] -** *identifies broad clinical indications consistent with around 15% patient need.*

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[7] Bengt Glimelius, et al. (2005) Number of Patients Potentially Eligible for Proton Therapy, Acta Oncologica, 44:8, 836-49

[8] https://dphconwebportal.ct.gov/Report/CONAttachment_Download?aid=9342

[9] Global Consensus (Lancet Oncology):
Yan S, Ngoma TA, Ngwa W, Bortfeld TR. (2023). Global democratisation of proton radiotherapy. *The Lancet Oncology*, Vol. 24, Issue 6, Pages e245–e254.

[10] Knottnerus, Professor J. A. *Proton Radiotherapy Horizon Scanning Report*. 14 Dec. 2009, www.healthcouncil.nl/binaries/healthcouncil/documenten/advisory-reports/2009/12/11/proton-radiotherapy/advisory-report-proton-radiotherapy.pdf. Accessed 4 June 2025.

[11] The Quest for Evidence for Proton Therapy: Model-Based Approach and Precision Medicine
Widder, Joachim et al. International Journal of Radiation Oncology, Biology, Physics, Volume 95, Issue 1, 30 – 36.

[12] Orecchia R, Fossati P, Rossi S. (2011). The national center for oncological hadron therapy: status of the project and future clinical use of the facility. Tumori Journal

4. **UK Expert Consensus[13] -** A recent consensus indicating ~13% as a practical median, aligned closely with the 15% international standard.

5. **Australian Consensus[14] -** *Australian guidelines estimating the practical use at around 5–15%.*

Regional Testing

The Dutch model, which includes use of the Horizon Scanning Report, has been explicitly tested and implemented in the Netherlands, where patient selection for proton therapy is based on individual Normal Tissue Complication Probability (NTCP) Modeling. This approach has been practically implemented and continues to guide clinical selection, demonstrating its effectiveness and reliability in clinical decision-making and resource allocation for proton therapy.

Indication of 37%

The 37% growth in proton therapy volume is derived from the ACS anticipated growth rate of cancer, which on an annual basis over the next 10 years is expected to be 3.2% per year, and the probability that the percentage of both radiation and proton therapy patients would grow at a similar rate. Please refer to Exhibit F Page 5 of the DoN Application which provides estimates by tumor type for 2024, 2029, and 2034.

QUESTION

4. **Exhibit G and page 14.** The estimates that 15% of <u>all</u> cancer patients would meet the clinical criteria for Proton Beam is not consistent with the previous models whereby 15 % of only Radiation Therapy patients would meet the criteria. Please explain.

RESPONSE

Upon reviewing the data presented in Exhibit G (page 14) of the DoN application, we have updated the second methodology to estimate the number of patients appropriate for proton therapy. The revised estimate assumes that 15% (489) of new cancer patients residing in Worcester County would be suitable candidates for proton therapy.

This percentage produces patient population estimates that are consistent with data derived from the second methodology outlined in Exhibit F and page 13.

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[13] Burnet NG, Mee T, Gaito S, et al. (2022). Estimating the percentage of patients who might benefit from proton beam therapy instead of X-ray radiotherapy. *British Journal of Radiology*, 2022, DOI: 10.1259/bjr.20211175

[14] Ahern V. (2021). Selecting patients for proton beam therapy. *Journal of Medical Radiation Sciences*, 68(1):2-3

Below is an updated Exhibit G estimating both the number of new cancer patients who would need some form of radiation therapy (RT) and the number of new cancer patients who would clinically benefit from proton therapy, using the same overall percentages as Exhibit F.

The updated results suggest that the total statewide number of patients who would benefit from proton therapy treatment is 3,877. Within Worcester County, an estimated 489 patients would benefit from proton therapy per year which does not include patients from the three towns in Norfolk County and 14 towns in Middlesex County that UMMH also serves.

Based on publicly reported data from Particle Therapy Co-Operative Group, the total average number of patients receiving proton therapy in Boston was approximately 640 patients per year over a 3-year period from 2021 to 2023.[15] Utilizing the results from the two different methodologies illustrated in Exhibits F and the revised Exhibit G, UMMH projects that there are 4,432 to 3,877 patients who would benefit from proton therapy and be suitable for proton therapy per year. Using the Particle Therapy Co-Operative Group data that indicates an average of 640 patients per year are receiving proton therapy, UMMH calculates that approximately an additional 3,792 to 3,237 patients would benefit from and be suitable for proton therapy per year. These calculations indicate that there is a significant unmet need for proton therapy treatment in Massachusetts that cannot be filled by the two units currently operating in Boston. Even if the only patients that are considered are those patients residing in UMMH's total service area or Worcester County, the data suggest an unmet need or limited access for the 743 (Exhibit F) to 489 (Exhibit G) patients who would benefit from and be suitable for proton therapy.

County	FIPS	2023 Rural-Urban Continuum Codes ([rural urban note])	Age-Adjusted Incidence Rate ([rate note]) - cases per 100,000	Lower 95% Confidence Interval	Upper 95% Confidence Interval	CI*Rank ([rank note])	Lower CI (CI*Rank)	Upper CI (CI*Rank)	Average Annual Count	# treated with RT	# treatable with PT
Massachusetts (7)	25000	N/A	437.2	435.2	439.2	N/A	N/A	N/A	38,523	25,682	3,877
US (SEER+NPCR) (1)	0	N/A	444.4	444.1	444.7	N/A	N/A	N/A	1,744,459	1,162,973	175,563
Plymouth County (7)	25023	Urban	476.5	469.1	484	1	1	2	3,415	2,277	344
Berkshire County (7)	25003	Urban	458.4	444.5	472.7	2	1	7	949	633	96
Worcester County (7)	25027	Urban	457.1	451.2	463.1	3	2	6	4,854	3,236	489
Norfolk County (7)	25021	Urban	454.3	448	460.6	4	2	6	4,198	2,799	422
Bristol County (7)	25005	Urban	453.8	446.8	460.9	5	2	7	3,357	2,238	338
Barnstable County (7)	25001	Urban	447.4	437.4	457.7	6	2	8	1,982	1,321	199
Hampden County (7)	25013	Urban	436.4	428.6	444.3	7	6	9	2,568	1,712	258

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[15] Particle Theory Co-Operative Group, 2025, www.ptcog.site.

Essex County (7)	25009	Urban	433.6	427.7	439.5	8		7	10	4,509	3,006	454
Nantucket County (7)	25019	Rural	419.9	375.8	468	9		2	14	70	47	7
Middlesex County (7)	25017	Urban	414	409.9	418.2	10		9	13	8,022	5,348	807
Franklin County (7)	25011	Rural	410.7	392.8	429.3	11		9	14	452	301	45
Hampshire County (7)	25015	Urban	406.8	393.8	420.2	12		9	14	823	549	83
Suffolk County (7)	25025	Urban	405.5	399.1	412	13		10	14	3,187	2,125	321
Dukes County (7)	25007	Rural	403.3	371.4	437.6	14		7	14	137	91	14