

Dana-Farber Cancer Institute, Inc.
DoN Application #DFCI-25090516-RS
Substantial Change in Service

DoN QUESTIONS #5

Responses should be sent to DoN staff at 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; only use PDF's if absolutely necessary. If "cutting and pasting" charts, provide them in a PDF so they can be clearly seen
- **Whenever possible, include a table with the response**
- **For HIPAA compliance Do not include numbers <11.**

Factor 1a: Patient Panel Need

1. What are the PBT coverage guidelines for patients insured through MassHealth and for patients with commercial insurance?

MassHealth does not have specific coverage guidelines for proton beam therapy.

Commercial insurance plans generally cover proton beam therapy coverage for specific conditions. For example, Aetna's guidelines set forth that proton beam therapy is medically necessary for the following conditions:

- Primary CNS tumors; *or*
- Head and neck tumors (T4 or unresectable, excluding T1-T2N0M0 laryngeal cancer); *or*
- Paranasal sinus, other accessory sinus, or nasopharyngeal tumors; *or*
- Skull-based tumors (e.g., chordomas or chondrosarcomas); *or*
- Malignancies in children (21 years of age and younger); *or*
- Esophageal cancer; *or*
- Malignancies requiring craniospinal irradiation (CSI) in persons with no active malignancy outside of the craniospinal axis; *or*
- Mediastinal lymphomas; *or*
- Thymomas and thymic carcinoma; *or*
- Thoracic sarcomas; *or*
- Nonmetastatic retroperitoneal sarcomas; *or*
- Ocular tumors, including intraocular/uveal melanoma (includes the iris, ciliary body and choroid); *or*
- Primary or metastatic tumors of the spine where the spinal cord tolerance would be exceeded with photon radiotherapy approaches; *or*
- Primary malignant or benign bone tumors; *or*

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- Reirradiation of an in-field or marginal recurrence being treated with curative intent, where other radiotherapy approaches would exceed acceptable constraints; *or*
 - Localized unresectable hepatocellular carcinoma (HCC) or intrahepatic cholangiocarcinoma in the curative setting when documentation is provided that sparing of the surrounding normal tissue cannot be achieved with standard radiation therapy techniques, including intensity-modulated radiation therapy (IMRT), stereotactic body radiation therapy (SBRT), selective internal radiation spheres, and transarterial therapy (for example, chemoembolization); *or*
 - Non-metastatic pelvic tumors that are advanced and unresectable, with significant pelvic or periaortic non-metastatic bulky nodes, where other radiotherapy approaches would exceed acceptable constraints; *or*
 - Persons with a single kidney or transplanted pelvic kidney with treatment of an adjacent target volume and in whom maximal avoidance of the organ is critical; *or*
 - Persons with genetic syndromes making total volume of radiation minimization crucial, such as, but not limited to NF-1 patients, BRCA1/2, deleterious ATM mutations, Li-Fraumeni, Lynch syndrome, and retinoblastoma; *or*
 - Pituitary neoplasms.
2. Responses to DoN Questions #1-updated, states that any licensed oncologist in Massachusetts may refer a patient for evaluation (pg.12).
- a. Explain the referral process for out-of-state referrals and/or patients.

The Applicant anticipates that out-of-state patients will be referred to the Center in the same manner as in-state patients—*e.g.*, directly by a physician, by phone, or through a self-referral.

3. What is the status of the Applicant’s clinical affiliation with Beth Israel Deaconess Medical Center (BIDMC) and Harvard Medical Faculty Physicians at BIDMC (HMFP) and will it have any effect on the Proposed Project?

The Applicant does not expect that the clinical affiliation with BIDMC and HFMP will have any effect on the Proposed Project. Following the determination of need by the Department for the Future Cancer Hospital,¹ as part of the clinical affiliation, the Applicant has continued to coordinate with both BIDMC and HFMP in the planning and development of the Future Cancer Hospital.

Factor 1b: Public health Value

4. Responses to DoN Questions #1-updated state that the Applicant will collect Patient-reported quality-of-life measures. Please list the specific measures that the Applicant will collect, as these measures will be included in the Applicant’s measures to evaluate the Proposed Project.

The Applicant expects to collect a standardized set of patient-reported outcome measures (“PROMS”) used in oncology to evaluate health-related quality of life, symptom burden, and

¹ Notice of Final Action, Dana-Farber Cancer Institute, Inc. (DoN Application #DFCI-23040915-HE), Mar. 21, 2025, <https://www.mass.gov/doc/decision-letter-pdf-dana-farber-cancer-institute/download>.

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functional status. These PROMS are based on the completion by patients of standardized questionnaires, collected at baseline, at defined intervals during active treatment, and at certain post-treatment follow-up time points.

The Applicant will assess the PROMs completion rate per location to ensure that patients are participating in PROMs. Additionally, the Applicant will assess toxicity and resolution of toxicity for every patient.

5. Describe anticipated proton-specific workflow for identifying preferred language and communication modalities.

The Center will follow the same approach as for all other services provided by the Applicant. Patients identify their preferred language for discussing medical issues when contacting the Applicant for their initial appointment or upon registration as a new patient.

6. Explain how language access provisions will be integrated into proton therapy workflow, including but not limited to, American Sign Language interpreters, tactile interpreters, CART services, large-print or plain-language materials, visual support, and so forth.

The Applicant offers interpreter services in three modalities: in-person, video remote interpreting, and over-the-phone interpreting. The automated workflow in Epic ensures that all patients identified as preferring a language other than English are presented to the interpreter services staff to assign an interpreter in advance of an initial appointment. The interpreter assigned is then listed in the patient's appointment as a joint provider.

7. Describe Dana Farber Cancer Institute's established processes to ensure that interpreters have specialized training in proton-related terms and are able to operate in such a specialized setting.

The Applicant anticipates that the interpreter services department will partner with the radiation oncology department to ensure that the team is prepared for proton therapy-related assignments.

8. Describe Dana Farber Cancer Institute's evidence-informed guidelines for staff to choose the most effective and appropriate modality for language services at the point of care.

Generally, the Applicant prioritizes providing patients with in-person interpreters. Video and phone interpreters are engaged when in-person interpreters are not available.

9. Describe Dana Farber Cancer Institute's current or planned adjustment in their MIS program structure to ensure:

- patient safety;
- timely response and delivery of language services, including ASL, to increasing demands;
- appropriate number of interpreters who are readily accessible when needed;
- translated pre-and-post proton documents for patients, including, but not limited to, pre and post procedural instructions;

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- guidance for selecting accessible pre-and-post treatment oral instructions; translated informed consent documents regarding procedure, and other relevant and legal information;
- and reasonable accommodation for patients with physical and cognitive disabilities.

- Patient Safety. The Applicant does not anticipate an adjustment will be needed in its MIS program. Currently, interpreters help the care team provide linguistically and culturally responsive care and services, which contributes to patient safety.

- Timely Response to Language Services. The Applicant does not anticipate an adjustment will be needed in its MIS program. Currently, appointments are scheduled in advance and interpreters are scheduled as soon as an appointment is made. Additionally, remote interpreter services are always available as a back-up for timely response and delivery.

- Appropriate Number of Interpreters. The Applicant does not anticipate an adjustment will be needed in its MIS program. Currently, the interpreter services department monitors volume and patient needs and will adjust appropriately by adjusting staff, per diem and partnering vendors.

- Translated Pre-and-Post Proton Documents, Oral Instructions, Informed Consent Documents, and Other Legal Information. The Applicant does not anticipate an adjustment will be needed in its MIS program. Currently, per the Applicant's policy, vital documents are translated into Spanish as this is the only language that meets the HHS guideline of the fewest of either (i) 1,000 patients or (ii) 5% of the patient population. Individual departments and the patient education team select (i) additional documents outside of vital documents for translation, and (ii) which documents may be translated into languages other than Spanish, as needed.

- Reasonable Accommodation for Patients. The Applicant uses an integrated, institute-wide accommodation(s) model to ensure patients with physical and cognitive disabilities receive timely, individualized support. The approach links ADA leadership with Medical Interpreter Services, Facilities & Real Estate, clinical teams, and specialized support programs so accommodation needs are identified early, documented in the electronic health record (Epic), and addressed consistently across settings. Together, these coordinated services focus on effective communication, accessible care environments, patient dignity, and shared understanding. Key elements include (i) proactive screening of patients and documentation in the electronic health record; (ii) maintaining physically accessible spaces; (iii) providing neuro-inclusive supports when requested, and (iv) cross-team collaboration among the ADA Coordinator, Interpreter Services, Social Work, the Neuro-Inclusive Program, Facilities, and clinical staff to meet accommodation needs to the greatest extent possible.