| *National Imaging Associates, Inc. | |
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| **Clinical guidelines:**<br>**PROTON BEAM RADIATION THERAPY** | **Original Date: June 2013** |
| **CPT codes: 77520,77522,77523,77525** | **Last Revised Date: May 2023** |
| **Guideline Number: NIA_CG_221** | **Implementation Date: January 2024** |

**GENERAL INFORMATION**

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

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Most requests for radiation therapy are addressed by NIA treatment site clinical guidelines. However, there may be requests that are not. For such requests, determinations will be made on a case-by-case basis utilizing the following guidelines (when applicable) but not limited to: National Comprehensive Cancer Network (NCCN), American Society for Radiation Oncology ASTRO (i.e., Model Policies; Evidence-Based Consensus Statement), ACR Appropriateness Criteria, American Society of Clinical Oncology (ASCO) and/or peer reviewed literature.

**MEDICALLY NECESSARY INDICATIONS FOR PROTON BEAM THERAPY (Will be reviewed on a case-by-case basis)**

**Treatment of the following in children less than 21 years of age**

- Primary or benign solid tumors (curative intent; occasional palliative treatment) when sparing of surrounding normal tissues cannot be achieved with photon therapy

**Treatment at any age[1]**

- Primary hepatocellular tumors treated with hypofractionated regimens
- Spinal tumors (primary or metastatic) where spinal cord has previously been treated with radiation or where the spinal cord tolerance may be exceeded with conventional treatment
- Tumors at the base of skull (chordoma, chondrosarcomas)

- Intraocular melanomas or other ocular tumors
- Patients with genetic syndromes making total volume of radiation minimization crucial, such as, but not limited to NF-1 patients and retinoblastoma patients
- Non-metastatic retroperitoneal sarcomas
- Re-irradiation cases (where cumulative critical structure dose would exceed tolerance dose)
- Malignant and benign primary CNS tumors: Consider proton therapy for patients with good long-term prognosis (grade 2 and 3 IDH-mutant diffuse glioma[2] and 1p19q codeleted tumors[3]) to reduce acute and late toxicity, especially for tumors located near critical OARs[4]
- Craniospinal RT: To reduce toxicity from CSI in adults, consider the use of IMRT or protons if available (for patients with positive CSF or known metastatic disease)[5]
- Advanced (e.g., T4) and/or unresectable head and neck cancers[6-17]
- Cancers of the paranasal sinuses and other accessory sinuses

**OTHER TREATMENT OPTIONS(Will be reviewed on a case-by-case basis)[1, 4, 18]**

For peer review purposes supporting documentation from the radiation oncologist is required and should include the clinical rationale for performing proton beam rather than 3-D conformal or IMRT or SRS.

Proton beam therapy has not been proven to be superior to conventional radiation therapy for all other indications including, but not limited to:

- Prostate cancer
- Breast cancer
- Lung cancer
- Colorectal cancer
- Cervical cancer
- Metastasis
- Gliomas (patients other than long-term prognosis (grade 2 and 3 IDH-mutant tumors [1] and 1p19q codeleted tumors))
- Soft tissue sarcoma (except for non-metastatic retroperitoneal sarcomas)
- Head and Neck (Non-T4 and resectable)
- Pelvic
- Gastric

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**BACKGROUND**

Proton beam therapy (PBT) is a type of external beam radiotherapy that uses charged particles. These particles have unique characteristics including limited lateral slide, scatter, and tissue in a defined range, going for maximum dose delivery over the last few millimeters of the particles' range. The maximum is called the Bragg peak. Proton beam irradiation when applied to treating cancer, uses different proton energy with Bragg peaks at various steps, enabling dose escalation to the tumor,

minimizing excess dose to normal surrounding tissue. Over the years, proton beam irradiation has been applied to treating tumors that require dose escalation to achieve a higher probability of care, as well as tumors requiring increased precision in dose deposition while protecting normal surrounding tissue. Proton therapy has an over 40-year history in treating cancer, yet to date, there have been few studies that show superiority to conventional photon beam irradiation, especially with modern techniques.

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**POLICY HISTORY**

| Date | Summary |
|---|---|
| May 2023 | • Edited: Malignant and benign primary CNS tumors: Consider proton therapy for patients with good long-term prognosis (grade 2 and 3 IDH-mutant diffuse glioma[2] and 1p19q codeleted tumors[3]) to reduce acute and late toxicity, especially for tumors located near critical OARs.<br>• Added reference: Radiation Therapy for IDH-Mutant Grade 2 and Grade 3 Diffuse Glioma: An ASTRO Clinical Practice Guideline, Halasz et al., Practical Radiation Oncology (2022) 12, 370-386<br>• Deleted Additional Resources<br>• Removed "physician review" language |
| January 2022 | • Under "Treatment at any age"<br>○ Added malignant and benign primary CNS tumors<br>○ Added craniospinal RT<br>○ Added advanced (e.g., T4) and/or unresectable head and neck cancers<br>○ Added cancers of the paranasal sinuses and other accessory sinuses<br>• Under "Other Treatment Options Requiring Physician Review"<br>○ Added Gliomas (patients other than long-term prognosis (grade 3 IDH-mutant tumors [1] and 1p19q codeleted tumors))<br>○ Added Head and Neck (Non-T4 and resectable) |

**Reviewed / Approved by NIA Clinical Guideline Committee:**

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