

Clinical Appropriateness Guidelines: Radiation Oncology

Proton Beam Treatment Guidelines

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Proprietary

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Description and Application of the Guidelines



AIM's Clinical Appropriateness Guidelines (hereinafter "AIM's Clinical Appropriateness Guidelines" or the "Guidelines") are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. As used by AIM, the Guidelines establish objective and evidence-based, where possible, criteria for medical necessity determinations. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To advocate for patient safety concerns
- To enhance the quality of healthcare
- To promote the most efficient and cost-effective use of services

AIM's guideline development process complies with applicable accreditation standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up to date clinical principles and best practices. Relevant citations are included in the "References" section attached to each Guideline. AIM reviews all of its Guidelines at least annually.

AIM makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of AIM's Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, AIM considers the Guidelines to be important, proprietary information of AIM, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of AIM.

AIM applies objective and evidence-based criteria and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The AIM Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. If requested by a health plan, AIM will review requests based on health plan medical policy/guidelines in lieu of AIM's Guidelines.

The Guidelines may also be used by the health plan or by AIM for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

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Proton Beam Radiation Therapy Considerations

Proton beam radiation therapy (PBRT), also known as proton radiation therapy or proton radiotherapy, is a type of external radiation treatment. Using a stereotactic planning and delivery system, positively charged subatomic particles (protons) are targeted to a specific tissue mass. A focused dose of radiation is delivered to the target area while surrounding healthy tissue receives minimal radiation. PBRT is an active area for clinical investigations, and recommendations for its use continue to evolve.

Proton beam radiation therapy should be administered as monotherapy.

PBRT may be appropriate in circumstances where IMRT or stereotactic would potentially damage critical structures. This technique of radiation delivery is being actively studied in other clinical scenarios, and its role in treatment for these situations remains unclear.

Therefore, PBRT should only be used for treating other malignancies in the context of a clinical trial, including:

- Breast cancer
- Lung cancer
- Pancreatic cancer
- Hepatocellular carcinoma
- Head and Neck cancer

Proton beam therapy has been evaluated in comparison to IMRT for the treatment of Prostate Cancer. Studies did not demonstrate superiority of protons over photons, but with greater risk of gastrointestinal toxicity. Given the lack of superiority in the context of greater toxicity and greater cost, the role of protons for prostate cancer treatment remains unclear, and is not recommended or supported outside of the context of a clinical trial or registry at this time.

PBRT may be appropriate for pediatric patients who are at high risk of developing secondary malignancies.

PBRT is not recommended for the treatment of neovascularization secondary to age-related macular degeneration (AMD).

Uses of Proton Beam Radiation Therapy

Central Nervous System Lesions

Ocular Melanomas

Pediatric Tumors

Proton Beam Indications

This guideline outlines different applications of proton beam radiation therapy in the treatment of malignant and benign tumors and arteriovenous malformations.

Central Nervous System

Arteriovenous Malformation (AVM)

Proton beam is appropriate for AVM when **ANY** of the following conditions are met.

- Intracranial AVM not amenable to surgical excision or other conventional forms of treatment **OR**
- Adjacent to critical structures such as the optic nerve, brain stem or spinal cord

Central Nervous System (CNS) Tumors

Proton beam is appropriate for CNS tumors when **ALL** the following conditions are met

- Including, but not limited to, primary or metastatic CNS malignancies, such as gliomas (**both must be met**)
 - When adjacent to critical structures such as the optic nerve, brain stem, or spinal cord **AND**
 - When other standard radiation techniques such as IMRT or standard stereotactic modalities would not reduce the risk of radiation damage to the critical structure

Proton Beam Indications

Pediatric CNS Tumors

Proton beam is appropriate for pediatric CNS tumors when the following condition is met

- Age < 21

Chordoma, Chondrosarcoma

Proton beam is appropriate for chordoma, chondrosarcoma when the following condition is met

- As postoperative therapy for individuals who have undergone biopsy or partial resection of a chordoma or low-grade (I or II) chondrosarcoma of the basisphenoid region (e.g. skull-base chordoma or chondrosarcoma), cervical spine, or sacral/lower spine and have residual, localized tumor without evidence of metastasis

Melanoma

Ocular Melanoma

Proton beam is appropriate for ocular melanoma when the following condition is met

- As primary therapy for melanoma of the uveal tract (including the iris, choroid, or ciliary body) involving tumors of up to 24 mm in largest diameter and 14 mm in height, and with no evidence of metastasis or extrascleral extension
 - Particularly when plaque brachytherapy is not a feasible option

Pediatric patients

All tumor types

Proton beam is appropriate for pediatric patients (age < 21) when the following condition is met

- To treat all pediatric tumors

Coding

CPT

77520..... PBRT; simple, without compensation
77522..... PBRT; simple, with compensation
77523..... PBRT; intermediate
77525..... PBRT; complex

Central Nervous System

Arteriovenous Malformation (AVM)

ICD-10 Diagnoses

Q28.2	Arteriovenous malformation of cerebral vessels
Q28.3	Other malformations of cerebral vessels

Central Nervous System (CNS) Tumors (excludes pituitary)

ICD-10 Diagnoses

C71.0 - C71.9	Malignant neoplasm of brain
C72.0 - C72.9	Malignant neoplasm of spinal cord, cranial nerves, & other parts of central nervous system
C79.31	Secondary malignant neoplasm of brain
C79.49	Secondary malignant neoplasm of other parts of nervous system
D09.8	Carcinoma in situ of other specified sites
D33.0 - D33.9	Benign neoplasm brain & other parts of central nervous system
D42.0 - D42.9	Neoplasm of uncertain behavior of meninges
D43.0 - D43.9	Neoplasm of uncertain behavior of brain & central nervous system
D49.6	Neoplasm of uncertain behavior of brain

Chordoma, Chondrosarcoma

ICD-10 Diagnoses

C41.2	Malignant neoplasm of vertebral column
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx
C41.9	Malignant neoplasm of bone and articular cartilage, unsp

Pediatric CNS Tumors

ICD-10 Diagnoses

Less than 21 member age exception

Melanoma

Ocular Melanoma

ICD-10 Diagnoses

C69.30	Malignant neoplasm of unspecified choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.90	Malignant neoplasm of unspecified site of unspecified eye

Pediatric Patients

Tumors- All types

ICD-10 Diagnoses

Less than 21 member age exception

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These Guidelines are a work in progress that may be refined as often as new significant data becomes available.

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