

Geisinger Health Plan Policies and Procedure Manual

Policy: MP226

Section: Medical Benefit Policy

Subject: Proton Beam Radiation

Applicable Lines of Business

Commercial	Х	CHIP	X
Medicare	Х	ACA	X
Medicaid	Х		

I. Policy: Proton Beam Radiation

II. Purpose/Objective:

To provide a policy of coverage regarding Proton Beam Radiation

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

- 1. Attachment a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
- 2. Exhibit a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. Reviewed the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury:
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking
into account both the functional capacity of the Member and those functional capacities that are appropriate for
Members of the same age

DESCRIPTION:

Proton beams are one of several types of subatomic particles that have been used the treatment of malignancies. Proton beams are particulate radiation therapy, which differs from photon and/or conventional electromagnetic radiation therapy because of its unique property of minimal dispersal as the beam passes through the tissue. This minimizes radiation exposure to the normal surrounding tissues. This therapy requires accurate localization of tumor and precise, reproducible positioning of the patient.

INDICATIONS: Requires Prior Authorization by a Plan Medical Director or Designee

Commercial Business Segment

Requests for proton beam radiation will be evaluated on a per-case basis for the following indications:

- Treatment of melanoma of the uveal tract (including iris, choroids and ciliary body); or
- Postoperative therapy in patients who have biopsy proven chordomas or chondrosarcomas in the skull base region or sphenoid spine; or
- Treatment of arteriovenous malformations (AVMs) of the brain adjacent to critical structures such as the optic nerve, brain stem or spinal cord not amenable to surgical excision or stereotactic radiation; or
- Pituitary Neoplasms; or
- Central nervous system lesions including but not limited to, primary or metastatic malignancies adjacent to critical structures such as the optic nerve, brain stem or spinal cord not amenable to surgical excision or stereotactic radiation
- Hepatocellular carcinoma (localized, unresectable) in the curative setting when sparing of the surrounding tissue cannot be achieved with standard radiation therapy techniques including intensity-modulated radiation therapy (IMRT), stereotactic body radiation therapy (SBRT), selective internal radiation spheres (SIRT), or trans-arterial chemoembolization, or those standard techniques are contraindicated.

Proton beam radiation therapy may be evaluated for coverage on a per-case basis for a diagnosis that is not listed above when documentation is if avoidance of the surrounding normal tissue cannot be adequately achieved with standard radiation therapy techniques including intensity modulated radiation therapy (IMRT)* and stereotactic body radiation therapy (SBRT)**.

* Please refer to MP192 for a description of coverage regarding Intensity Modulated Radiation Therapy

**Please refer to MP084 for a description of coverage regarding Stereotactic Radiosurgery

Medicaid Business Segment

Request for coverage will be considered on a per case basis through the program exception process.

Medicare Business Segment

Coverage is in accordance with the local Medicare carrier's coverage mandate on proton beam radiation therapy.

Indications for the Medicare Business Segment:

- Benign or malignant central nervous system tumors to include but not limited to primary and variant forms of astrocytoma, glioblastoma, medulloblastoma, acoustic neuroma, craniopharyngioma, benign and atypical meningiomas, and pineal gland tumors.
- Intraocular melanomas
- Pituitary neoplasms
- Benign or malignant conditions of the base of the skull or axial skeleton including but not limited to chordomas and chondrosarcomas
- Malignant lesions of the head and neck
- Lung Cancer, especially NSCLC

- Unresectable retroperitoneal sarcoma and extremity sarcoma
- Solid tumors in children up to age 18
- Prostate Cancer when the following criteria are met:
 - o Physician documentation of patient selection criteria (stage and other factors);
 - Documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits; and
 - Documentation of the specific reasons why Proton Beam was the treatment of choice for the specific patient.

In addition, Proton Beam Therapy is indicated for the Medicare Business Segment when:

- The Dose Volume Histogram (DVH) illustrates at least three (3) critical structures or organs protected by the use of Proton Beam Therapy
- The dose to control or treat the tumor cannot be delivered without exceeding the tolerance of the normal tissue
- There is documented clinical rationale that doses generally thought to be above the level otherwise attainable with other radiation methods might improve control rate;
- There is documented clinical rationale that higher levels of precision associated with Proton Beam Therapy compared to other radiation treatments are clinically necessary.

EXCLUSIONS:

Charged-particle irradiation with proton beams using standard treatment doses is **NOT** considered medically necessary in patients with clinically localized prostate or rectal cancer. The **Geisinger Technology Assessment Committee** evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the superiority of this treatment on clinical outcomes when compared to other approaches including intensity modulated radiation therapy (IMRT) or conformal radiation therapy.

Charged-particle irradiation with proton beams is **NOT** considered medically necessary for indications not specifically outlined in this policy. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the superiority of this treatment on clinical outcomes when compared to other approaches including intensity modulated radiation therapy (IMRT) or conformal radiation therapy.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

77520 Proton treatment delivery; simple, without compensation

77522 Proton treatment delivery; simple with compensation

77523 Proton treatment delivery; intermediate

77525 Proton treatment delivery; complex

77399 Medical radiation physics, dosimetry and treatment devices, and special services

77299 Therapeutic radiology clinical treatment planning

77499 Therapeutic radiology treatment management

S8030 Scleral application of Tantalum ring(s) for localization of lesions for proton beam therapy

170.2 Malignant neoplasm vertebrae 190.0-190.9 Malignant neoplasm of eye

191.5 Malignant neoplasm of the ventricles192.2 Malignant neoplasm of the spinal cord

194.0-194.4 Malignant neoplasm of adrenal gland, parathyroid gland, pituitary gland and craniopharyngeal duct, pineal

gland

747.81 Anomalies of cerebrovascular system

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL.

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/15/09

Revised: 2/11 (indications), 2/12 (indications), 2/14, 2/16 (Indications); 1/19 (indications); 1/21 (clarify exclusions);

1/22(add HCC indication)

Reviewed: 2/10, 2/13, 2/15, 2/17,1/18, 1/20, 1/23, 1/24

CMS UM Oversight Committee Approval: 12/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health

Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.