

Evolut Clinical Guideline 7001 for Proton Beam Radiation Therapy and Neutron Beam Radiation Therapy Services

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STATEMENT

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. This guideline is not a prescription for treatment. All individual treatment decisions are the responsibility of the treating physician.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

This guideline provides indications for the use of Proton Beam Therapy (PBRT) and Neutron Beam Therapy (NBRT).

Clinical Reasoning

This guideline considers treatment endorsed by professional organizations (i.e., the American Society for Radiation Oncology and the National Comprehensive Cancer Network). It approves many treatment regimens that fall within that guidance, but it is also modified by significant factors such as toxicity and the level of available medical evidence.

Special Note

See Legislative Language for specific mandates for Oregon, Tennessee, and Washington.

INDICATIONS

Proton Beam Radiation Therapy (PBRT)

PBRT Indications for Specific Cancer Types

The following adult cancer types are indicated for treatment with PBRT:

- Liver (Hepatocellular Carcinoma) and intrahepatic bile duct cancers ^(1–6)
- Paranasal Sinus ^(7,8)

- Nasopharynx ^(9,10)
- Maxillary Sinus ^(8,11)
- Ethmoid Sinus ^(8,11)
- Cavernous Sinus ^(8,11)
- Chordomas and Chondrosarcomas Spine and Base of Skull ⁽¹²⁾
- Meningioma, benign and non-benign ^(12–15)
- Arteriovenous Malformations (AVM) ^(16,17)
- Acoustic Neuroma ^(18–20)
- Pituitary Adenoma ^(21,22)
- Intraocular (Uveal) Melanoma ^(23,24)
- Other brain or spinal tumors that are adjacent critical structures such as an optic nerve, optic chiasm, brain stem, or spinal cord AND cannot be sufficiently spared using IMRT or SRS treatment.

PBRT Indications for Pediatric Cancers

- PBRT will be approved for ALL pediatric patients (≤ 18 years old). Patients < 21 years old with cancers that display the same histology as common pediatric cancers may be approved (following manual review by a physician reviewer) in select cases. ^(25,26)

PBRT Indications for Cases of Re-Irradiation

Definitions

Re-irradiation is defined as the use of additional radiation treatment to treat an area of the body that has already received prior radiation to that same area.

The term "re-irradiation" does NOT apply to situations where a patient has received radiation treatment to one area of the body (i.e. the lung) and now requires radiation to a completely separate area of the body (i.e. the brain).

PBRT will be approved for ALL patients who have received any previous radiation to an anatomic location and who now require an additional course of radiation to that same anatomic area.

The radiation dose and the number of fractionations prescribed for each patient receiving re-irradiation will be different and based on that patient's prior treatment history. The dose and the number of fractionations will be left to the discretion on the treating physician and when possible, based on peer reviewed literature. ^(27,28)

Neutron Beam Radiation Therapy (NBRT)

NBRT Indications for Specific Cancer Types

- Salivary gland cancers that are:

- Unresectable or recurrent ⁽²⁹⁾

LEGISLATIVE LANGUAGE

State of Oregon

ORS 743A.130 ⁽³⁰⁾

Applicable to all lines of business

ORS 743A.130

Proton beam therapy

(1) A health benefit plan, as defined in ORS 7438.005 (Definitions), that provides coverage of radiation therapy for the treatment of prostate cancer must provide coverage for proton beam therapy for the treatment of prostate cancer on a basis no less favorable than the coverage of radiation therapy.

(2) The coverage of proton beam therapy under subsection (1) of this section may be subject to prior authorization, as defined in ORS 7438.001 (Definitions), or other utilization review, as defined in ORS 7438.001 (Definitions), if the prior authorization or utilization review applied to proton beam therapy is no more restrictive than the prior authorization or utilization review applied to radiation therapy.

(3) This section is exempt from ORS 743A.001 (Automatic repeal of certain statutes on individual and group health insurance). [2019 c.466 §2; 2021 c.384 §1]

Note: 743A.130 (Proton beam therapy) was added to and made a part of the Insurance Code by legislative action but was not added to ORS chapter 743A or any series therein.

See Preface to Oregon Revised Statutes for further explanation.

State of Tennessee

TN Code 56-7-2327 ⁽³¹⁾

Applicable to commercial lines of business

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 56-7-2327, is amended by deleting the section and substituting:

(a) This section is known and may be cited as the "Proton Therapy Access Act."

(c) The state group insurance program shall cover a physician prescribed hypofractionated proton therapy protocol to deliver a biological effective dose by paying the same aggregate amount as would be paid for the delivery of the same biological effective dose with a standard radiation therapy treatment protocol delivered with IMRT for the same

indication if the following conditions are satisfied:

- (1) Coverage is provided to an eligible patient who is being treated as part of a clinical trial or registry;
- (2) The eligible patient is diagnosed with a cancer type or indication that can be treated with a hypofractionated proton therapy protocol;
- (3) The radiation oncologist prescribing the hypofractionated proton therapy protocol is board certified or board eligible in the specialty of radiation oncology; and
- (4) The hypofractionated proton therapy protocol is administered in a facility in this state.

State of Washington

HTCC Coverage Determination 20190517A ⁽³²⁾

Applicable to all lines of business

Number and coverage topic:

20190517A – Proton beam therapy – re-review

HTCC coverage determination:

Proton beam therapy is a **covered benefit** for children/adolescents less than 21 years old.

Proton beam therapy is a **covered benefit with conditions** for individuals 21 years old and older, consistent with the criteria identified in the reimbursement determination.

HTCC reimbursement determination:

Limitations of coverage:

For individuals 21 years old and older proton beam therapy is a covered benefit with conditions for the following primary cancers:

- Esophageal
- Head/neck
- Skull-based
- Hepatocellular carcinoma
- Brain/ spinal
- Ocular
- Other primary cancers where all other treatment options are contraindicated after review by a multidisciplinary tumor board.

Non-covered indicators:

Proton beam therapy is not covered for all other conditions.

CODING AND STANDARDS

Codes

32701, 61796, 61797, 61798, 61799, 61800, 63620, 63621, 77014, 77261, 77262, 77263, 77280, 77285, 77290, 77293, 77295, 77299, 77300, 77301, 77321, 77331, 77332, 77333, 77334, 77336, 77338, 77370, 77372, 77373, 77387, 77399, 77423, 77427, 77432, 77435, 77470, 77499, 77520, 77522, 77523, 77525, G0339, G0340, G6001, G6002, G6017

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

SUMMARY OF EVIDENCE

Proton Beam Radiation Therapy (PBRT) ⁽²⁷⁾: PBRT is indicated for specific cancer types due to its precision in targeting tumors while minimizing damage to surrounding healthy tissues. This therapy is particularly beneficial for cancers located near critical structures that cannot be sufficiently spared using other radiation treatments like IMRT or SRS.

PBRT is also approved for all pediatric patients (≤ 18 years old) and for patients < 21 years old with cancers that display the same histology as common pediatric cancers. Additionally, PBRT is indicated for cases of re-irradiation, where additional radiation treatment is required for an area that has already received prior radiation.

Neutron Beam Radiation Therapy (NBRT) ⁽²⁹⁾: NBRT is indicated for salivary gland cancers that are unresectable or recurrent. This therapy is beneficial due to its ability to deliver high-energy neutrons that can effectively target and destroy cancer cells.

ANALYSIS OF EVIDENCE

When choosing either proton beam radiation therapy (PBRT) or neutron beam radiation therapy (NBRT), several factors should be considered to ensure the most effective and appropriate treatment for the patient. ^(27,29)

1. Cancer Type and Location:

- PBRT is particularly beneficial for cancers located near critical structures that cannot be sufficiently spared using other radiation treatments like IMRT or SRS. It is indicated for specific cancer types such as liver cancer, paranasal sinus cancer, chordomas, chondrosarcomas, meningiomas, arteriovenous malformations, acoustic neuromas, pituitary adenomas, intraocular melanomas, and other brain or spinal tumors adjacent to critical structures.
- NBRT is indicated for salivary gland cancers that are unresectable or recurrent.

2. Patient Age:

- PBRT is approved for all pediatric patients (≤ 18 years old) and for patients < 21 years old with cancers that display the same histology as common pediatric cancers.

3. Re-Irradiation:

- PBRT is indicated for cases of re-irradiation, where additional radiation treatment is required for an area that has already received prior radiation.

4. Toxicity and Side Effects:

- The choice of PBRT or NBRT should consider the potential toxicity and side effects associated with each therapy. PBRT is known for its precision in targeting tumors while minimizing damage to surrounding healthy tissues.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> ● Removed unnecessary background and informational text ● Updated citations ● Removed Oropharynx Cancer from Indications ● Added Clinical Reasoning Section ● Added legislation for state of TN ● Added Summary of Evidence and Analysis of Evidence ● Removed legislative language for Oklahoma, Virginia, Illinois
August 2024	<ul style="list-style-type: none"> ● This guideline replaces Evolent Clinical Guideline 229 for Neutron Beam Therapy (NBT) ● This guideline replaces Evolent Clinical Guideline 221 for Proton Beam Radiation Therapy ● This guideline replaces Evolent Utilization Management External Radiation Therapy Policy 2010 for Neutron Beam and Proton Beam Radiation Therapy

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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