The National Association for Proton Therapy

# Model Policy

## Coverage of Proton Therapy

Endorsed by:

National Association for Proton Therapy
Particle Therapy Cooperative Group – North America
The Alliance Dedicated Cancer Centers

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## INTRODUCTION

Proton therapy is a technologically advanced method to deliver curative radiation doses to cancerous tumors. The unique characteristics of how protons interact within the human body allow the delivery of radiation doses to a tumor while reducing radiation doses to surrounding healthy tissues and organs, resulting in fewer complications and side effects than standard radiation therapy. Understanding how proton therapy works provides patients, providers, payers, policymakers, and other stakeholders with insight into the clinical advantages of this treatment modality.

Fundamentally, all tissue cells are made up of molecules with atoms as their basic building blocks. In the center of every atom is the nucleus. Orbiting the nucleus of the atom are negatively charged electrons. When energized protons pass near orbiting electrons, the positive charge of the protons attracts the negatively charged electrons, pulling them out of their orbits. This is called ionization. Because of ionization, the radiation damages molecules within the cells, especially the DNA. Damaging the DNA destroys specific cell functions, particularly the ability to divide or proliferate. While both normal and cancerous cells go through this repair process, a cancer cell's ability to repair molecular injury is frequently inferior. As a result, cancer cells sustain more permanent damage and subsequent cell death than occurs in the normal cell population.

Both standard radiation therapy and proton therapy work on the same principle of damaging cellular DNA. The major advantage of proton therapy over standard radiation therapy, however, is that protons slowly deposit their energy as they travel towards the cancerous tumor and then, due to a unique physical characteristic called the Bragg Peak, deposit the majority of the radiation dose directly in the tumor and travel no further through the body. This significantly minimizes the amount of unnecessary radiation delivered to healthy tissues and organs, thereby reducing unwanted complications and side effects. Standard radiation therapy utilizes x-rays which deposit the majority of the radiation dose immediately upon entering the body while traveling to the tumor. Unlike protons, after depositing radiation dose in the tumor, the x-rays continue traveling through the body until exiting out the other side, resulting in the delivery of unnecessary radiation to healthy tissues and organs.

Proton therapy may be delivered in two methods: passive scattering (also known as single and double scattering) and active scanning (also known as uniform and “pencil beam scanning”). With passive scattering and uniform scanning, apertures and compensators are used to shape and fine tune the depth of the proton beam. With pencil beam scanning, there is generally no need for apertures and compensators, as the dose is “painted” in layers, producing more proximal conformity of the dose distribution as well as modulation of the dose within a field, referred to as “intensity modulated proton therapy” or IMPT.

## POLICY DESCRIPTION

This document is intended as a model coverage policy for proton therapy. This model policy identifies under which clinical indications such therapy is clinically appropriate to administer to patients. The use of proton therapy in patients with the indications delineated in the policy is

supported by references to peer-reviewed, scientific literature. The applicable ICD-10-CM codes that correlate to each of the clinical indications are listed in **Appendix 1**.

## INDICATIONS FOR COVERAGE

Based on the peer-reviewed scientific literature references listed in **Appendix 2**, proton therapy is considered medically necessary for the following conditions:

- **Ocular tumors*,+**, including *intraocular melanomas and ocular adnexal tumors* such as *tumors of the lacrimal gland*;
- **Malignant or benign conditions of the base of the skull or axial skeleton*,+** including but not limited to *chordomas, chondrosarcomas, and osteosarcomas*;
- **Malignant or benign central nervous system tumors*,+**;
- **Malignant or benign tumors of the spine or around the spinal cord*** where the radiation tolerance of the spinal cord may be comprised or previous radiation has occurred;
- **Hepatocellular carcinoma*,+ and cholangiocarcinoma**;
- **Malignant or benign pediatric solid tumors*** in children up to age 18;
- **Malignant lesions of the head and neck*,**,+**, including but not limited to *nasopharyngeal, oropharyngeal, paranasal sinus and nasal cavity cancers* as well as *benign head and neck tumors* with long anticipated survivorship, such as *glomus tumors*;
- **Gastrointestinal cancers**** including *pancreatic, rectal and anal tumors*;
- **Retroperitoneal sarcomas*,+**;
- **Prostate Cancer**,+** (non-metastatic);
- **Breast Cancer****;
- **Thoracic tumors**,+** including *lung cancers, esophageal cancers++, mediastinal lymphomas, thymomas, sarcomas, and mesothelioma*;
- **Hodgkin's Lymphoma**,+**;
- **B-Cell Lymphomas+**; and,
- **Re-irradiation*** of previously treated areas where the radiation dose tolerance of critical organs and structures would be exceeded.

In addition, Proton Therapy is indicated when:

- The Dose Volume Histogram (DVH) illustrates at least one (1) or more critical structures or organs that must be considered at risk in or adjacent to the treatment volume to be protected by the use of proton therapy;
- There is documented clinical rationale that doses generally thought to be above the level otherwise attainable with other radiation methods might improve control rates, and/or;

- Other radiation therapy treatment plans (e.g., photon based treatment plans) would have a greater probability of causing clinically meaningful acute and late normal tissue toxicity;
- The proposed treatment volume or an immediately adjacent volume has been previously irradiated, and the dose must therefore be tightly conformed to avoid exceeding the tolerance dose of nearby normal organs and tissues and proton therapy would result in less risk; or
- There is documented clinical rationale that the higher levels of precision associated with proton therapy compared to other radiation treatments are clinically necessary.

Other factors considered favorable for coverage for additional indications than those listed above include enrollment of the patient in a clinical trial or an appropriate prospective clinical registry for planned assessment and publication. Any denials for indications not listed in this policy can have medical documentation and adequate literature submitted in the appeals process for potential coverage.

## LIMITATIONS FOR COVERAGE

- Proton therapy is generally not indicated for cancers that are *widely disseminated*.
- For the treatment of primary lesions, the intent of treatment should be curative; in the retreatment scenario, *long-term durable local control is an acceptable intent*.
- For the treatment of recurrent or metastatic lesions, there should be the expectation at the time of treatment of a *long term benefit* (greater than 12 months of life expectancy).

## PROTON THERAPY TREATMENT DELIVERY CPT® CODES

- **77520 Proton treatment delivery; simple, without compensation** – Treatment to a single treatment area utilizing a single non-tangential/oblique port, custom block, without compensation.
- **77522 Proton treatment delivery; simple, with compensation** – Treatment to a single treatment area utilizing a single non-tangential/oblique port, custom block, with compensation.
- **77523 Proton treatment delivery; intermediate** – Treatment delivery to one or more treatment areas utilizing two or more ports or one or more tangential/oblique ports, with custom blocks and compensations.
- **77525 Proton treatment delivery; complex** – Treatment delivery to one or more treatment areas utilizing two or more ports per treatment area with matching or patching fields and/or multiple isocenters, with custom blocks and compensators.

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* *American Society of Radiation Oncology (ASTRO) 2017 Model Policy supports the use of proton therapy.*

** *American Society of Radiation Oncology (ASTRO) 2017 Model Policy supports the use of proton therapy under a Coverage with Evidence Development model.*

\+ *National Comprehensive Cancer Network (NCCN) Guidelines supports the use of proton therapy when appropriate.*

\++ *National Comprehensive Cancer Ntwork (NCCN) Guidelines supports the use of proton therapy within a clinical trial.*

- **77373 Stereotactic body radiation therapy** – Treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions.

## POLICY DISCLAIMERS

While this model coverage policy for proton therapy is an excellent guide for clinicians and payers alike, it should not be used as a comprehensive tool. As technologies and best practices in our medical field change and evolve, so too will this model coverage policy. In addition, clinical decision-making regarding the appropriate application of proton therapy for a given patient should remain solely with the patient with guidance from the patient's treating physician. We acknowledge that the information provided in this document is focused on the typical patient's clinical indications and there will always be patients who present with indications or symptoms not captured within this model coverage policy. In those cases, it is our expectation that providers will adhere to literature based guidelines and provide the payer with as much clinical information as possible to support the use of performing a proton therapy procedure in an atypical patient.

This policy covers the proton therapy delivery service itself and is not intended to cover the entire scope of services associated with proton therapy (i.e., treatment planning, simulation and imaging, contouring, radiation dose prescribing, dosimetric planning and calculations, and patient specific dose verification). These services may have separate coding and reporting requirements that are not addressed in this policy.

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