Department:	Medical Management	**Original Approval:**	06/11/2015
Policy #:	MM153	**Last Approval:**	07/24/2018
Title:	Proton Beam Therapy		
Approved By:	UM Committee		

REQUIRED DOCUMENTATION FOR REVIEW:

Chart notes including History, Previous treatments, Physical exam, Imaging studies, Pathology and pertinent labs, Diagnosis and Plans for treatment.

POLICY:

For WA Apple Health Members:

CHPW uses the Washington State Health Care Authority Health Technology Assessment Program criteria for consideration of coverage of this procedure.

Link to Final Findings and Decision:
https://www.hca.wa.gov/assets/program/pbt_final_findings_decision_071114[1].pdf

For Medicare Advantage Members:

In the absence of NCD or LCD guidance, CHPW uses MCG, current edition, (Proton Beam Therapy, ACG: A-0389 (AC))

BACKGROUND

Topic Summary

It is estimated that nearly 14 million Americans are cancer survivors and that 1.7 million new cases will be diagnosed in 2013. Among the treatment options for cancer, radiation therapy is commonly employed; an estimated 50% of patients receive radiation therapy at some point during the course of their illness.

The use of external beam radiation therapy (EBRT) for the treatment of cancer dates back more than 100 years. Conventional EBRT is comprised of photon (X-ray) beams and is targeted directly at solid tumors to destroy cancerous cells. While photons are an effective means of eliminating malignant cells, these high-energy x-rays also cause damage to normal tissue along the beam path as they enter and exit the body. Toxicities associated with injury to normal tissue include those specific to the anatomic location being treated (e.g., incontinence in patients treated for prostate or gynecological cancers) as well as general effects such as nausea and fatigue. Exposure of normal tissues to radiation also may increase the future risk of secondary malignancies.

To address these concerns, advanced techniques in the application of X-rays to reduce toxicity and more accurately target the cancer have been developed, including intensity-modulated radiation therapy (IMRT), CT-based 3D-conformational radiation therapy (3D-CRT), and stereotactic radiation therapy. An

alternate approach to the use of photons is the use of heavy particles such as electrons, neutrons and protons as agents of radiation energy deposition. Of particular interest is proton beam therapy (PBT), as the physical properties of protons permit dose delivery at specific tissue depths. Protons deliver a low dose of energy when entering the body and deposit the bulk of their radiation energy at the end of their range of penetration, a phenomenon known as the "Bragg peak." By focusing delivery of radiation to the target tumor, it is believed that PBT may reduce toxicity associated with normal tissue damage.

Policy Context
PBT has the potential to be an important therapeutic option for specific cancers given its physical properties. Interest in its use for a variety of clinical applications has grown substantially in recent years. There are 12 operating PBT facilities in the U.S., with the most recent facility opening in Seattle, WA in March 2013. Fifteen additional centers are currently under construction or in development in the U.S.

However, there are significant uncertainties with the use of PBT. Some of these are technical. For example, treatment planning is more complex with protons due to the lack of an exit dose, and may be affected by organ motion, anatomical variation, and other factors. In addition, there are questions regarding how the more targeted treatment delivery with PBT translates into comparative effects on cancer control, toxicity, and health-related quality of life relative to other treatment approaches. These uncertainties have led to variability in coverage policy for PBT among public and private payers.

In addition, the cost of treatment with PBT is substantially higher than for other EBRT modalities such as IMRT and 3D-CRT. Proton facilities must be able to house large cyclotrons to effectively accelerate protons for treatment delivery, and can cost anywhere from $25 million to over $200 million to construct. In addition, Medicare payments for each PBT session are 4-8 times higher than for other EBRT modalities.

Primary Criteria Ranking
Safety = Medium
Efficacy = High
Cost = High

DEFINITIONS
Enter all definitions here.

INDICATIONS/CRITERIA

Medicaid Members	***Continue to criteria for approval below.***
Medicare Members	

For WA Apple Health Members:

https://www.hca.wa.gov/assets/program/pbt_final_findings_decision_071114[1].pdf
(HTA, 20140516A – Proton Beam Therapy, July 11, 2014)

Limitations of Coverage
Proton Beam Therapy is a **covered benefit with conditions** for:

- Ocular cancers
- Pediatric cancers (e.g., medulloblastoma, retinoblastoma, Ewing's sarcoma)
- Central nervous system tumors
- Other non-metastatic cancers with the following conditions:
  - Patient has had prior radiation in the expected treatment field with contraindication to all other forms of therapy, and
  - At agency discretion.

Non-Covered Indicators
Proton Beam Therapy is **not covered** for all other conditions.

For Medicare Advantage members:
CHPW uses MCG current edition: ACG: A-0389 (AC)

SPECIAL CONSIDERATIONS
Enter all special considerations here.

LIMITATIONS/EXCLUSIONS
Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

CFR		
WAC		
RCW		
Contract Citation	☒ WAH	11.2.9 The Contractor shall follow the coverage decisions of the Health Technology Assessment (HTA) program (chapter 182-55 WAC)
	☒ IMC	
	☒ MA	
Other Requirements		
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
05/21/2015	Policy created	Kate Brostoff, MD
06/11/2015	Approval	MMLT
08/08/2016	References updated with active links. CMMS changed to CMS	Cyndi Stilson, RN
08/08/2016	Reviewed	Jane Daughenbaugh, RN
08/09/2016	Reviewed – no changes	Victor Collymore, MD
08/09/2016	Approval	MMLT
08/15/2017	Updated link to HCA Health Technology Assessment.	Cyndi Stilson, RN
08/18/2017	Approval	MMLT
03/27/2018	Changed from UM131 to MM153	Cindy Bush
04/06/2018	Transferred to new template	Cindy Bush
07/20/2018	Updated and added requirements for documentation. Added the LCD for proton	LuAnn Chen, MD

	beam therapy for uveal melanoma.	
07/24/2018	Approval	UM Committee