



CIGNA MEDICAL COVERAGE POLICY

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Subject Proton Beam Therapy for Intracranial and Skull Base Tumors

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Coverage Policy

CIGNA covers proton beam therapy as medically necessary for the treatment of intracranial and skull base tumors when radiation therapy is indicated and recommended by the treating physician.

General Background

Proton beam therapy (PBT) is a form of stereotactic radiosurgery that delivers a focused dose of radiation energy to the targeted area while surrounding normal tissue receives minimal radiation. PBT releases its highest percentage of energy at the end of its path (i.e., Bragg peak), depositing 100% of the dosage at the targeted tissue. In contrast, conventional external beam radiation therapy (EBRT) delivers radiation to diseased and normal tissue, and targeted tissue receives 60–70% of the intended dose (Smith, et al., 2006; MacDonald, et al., 2006; Chen and Girvigian, 2005).

PBT is an accepted treatment option for benign or malignant tumors located within the skull (i.e., intracranial) and tumors located at the base of the skull (i.e., skull base tumors). Benign tumors include: acoustic neuromas,

vestibular schwannomas, neurolemmomas, chondromyxoid fibromas, craniopharyngiomas, meningiomas, and pituitary adenomas. Malignant intracranial tumors include brain metastases, chondrosarcomas, chordomas, sinonasal tumors, and medulloblastomas. Glioma is a general category of malignant brain tumors that includes astrocytomas (i.e., pilocytic, low-grade, anaplastic and glioblastoma multiforme), primitive neuroectodermal tumors, oligodendrogliomas, ependymomas, subependymoma, brain stem gliomas, optic gliomas and mixed gliomas.

The treatment choice for intracranial and skull base tumors depends upon the location, size and grade of tumor, as well as the patient's age and general health status. Ideally, the tumor can be surgically excised with follow-up treatment involving chemotherapy and/or external whole beam radiation therapy, and/or stereotactic radiation therapy including PBT.

U.S. Food and Drug Administration (FDA)

Proton beam therapy systems are approved by the FDA 510(k) process as a "medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation" (FDA, 2006). Examples of such systems are the Optivus Proton Beam Therapy System (Optivus Technology Inc., Loma Linda, CA) and the IBA Proton Therapy System-Proteus 235 (Ion Beam Applications S.A., Philadelphia, PA).

Literature Review

Evidence in the published, peer-reviewed literature and professional societies support PBT for the treatment of intracranial and skull base tumors. Studies are primarily in the form of case series and retrospective reviews. Overall survival, local control, progression, and recurrence rates varied based on the type and location of tumors. Studies comparing PBT to conventional external beam radiation therapy and other types of stereotactic radiosurgery are lacking.

Acoustic Neuroma: PBT is an established treatment option for acoustic neuromas, also called vestibular schwannomas or neurolemmomas. Case series and retrospective reviews reported tumor regression and/or stability in the majority of subjects (e.g., 97%) for 12–102.6 months following PBT. Five-year actuarial facial and trigeminal nerve function preservation rates were 91.1% and 89.4%, respectively (Weber, et al., 2003; Harsh, et al., 2002; Bush, et al., 2002).

In their guideline on stereotactic radiosurgery for the treatment of vestibular schwannomas, the International RadioSurgery Association (2006) stated that stereotactic radiosurgery (including PBT) is "typically employed as the first management option for patients with small to medium size tumors (without brainstem compression)", is used "to control growth of recurrent or residual tumors after surgical resection", and "may be especially suitable for patients who desire preservation of neurological function (cochlear, facial nerve) and a high rate of tumor growth control". They pointed out that fractionated PBT with a frameless system delivers a higher dose than single dose treatment. The higher dosage increases the risk of complications, such as hearing loss; facial numbness, pain, and weakness; and temporary unsteadiness.

Brain Metastases: Although there is insufficient evidence in the published peer-reviewed literature evaluating PBT for the treatment of brain metastases, PBT is an accepted, alternate focal therapy for the treatment of brain metastases and may be the treatment option of choice.

The National Comprehensive Cancer Network[®] (2010) states that stereotactic radiosurgery[®] may be appropriate treatment for brain metastasis following surgical excision. They state that patients who are not surgical candidates or who have multiple brain metastases should receive either stereotactic radiosurgery or whole brain radiation therapy. According to NCCN[®], stereotactic radiosurgery "can be used in the initial treatment of patients with only one or 2 appropriate brain metastases (that is, small, deep) or in those who relapse. The survival rates can be comparable to those for surgical resection". NCCN did not discuss the different types of stereotactic radiosurgery.

In their radiosurgery practice guideline for the use of stereotactic radiosurgery for patients with metastatic brain tumors, the International RadioSurgery Association (2008) stated that radiosurgery (including PBT) "as the sole initial management or as a boost before or after WBRT [whole brain radiation therapy] has emerged as a widely practiced treatment modality for brain metastases". Radiosurgery is proposed to achieve improved local brain tumor control and improve survival "in selected patients in whom the predominant problem is brain disease

rather than extracranial disease". Following surgery or WBRT, PBT may also be used as salvage treatment in progressive intracranial disease.

Chondrosarcoma and Chordoma: Due to the location of chondrosarcomas and chordomas, complete surgical excision can rarely be achieved. Because these tumors are relatively radioresistant, the high-dose irradiation needed to eradicate the tumor is often not feasible and safe with conventional external beam radiation therapy. Therefore, PBT therapy has become an established treatment option. Systematic reviews, case series (Amichetti, et al., 2010; Amichetti, et al., 2009; Habrand, et al., 2008; Weber, et al., 2005; Noel et al., 2005; Noel, et al., 2002; Hug, et al., 2002) and retrospective reviews (Igaki, et al., 2004) support PBT for the treatment of chondrosarcoma and chordoma. Studies have reported an overall survival rate of up to 94.3%, a five-year survival rate of 99%–100%, and progression-free survival rates of 81% for chondrosarcomas and 77% for chordomas. Outcomes following conventional radiotherapy included five- and ten-year overall survival rates of 53.5% and 50.3%, respectively.

The National Cancer Institute (2010) states that standard treatment for chordomas includes surgery, which is generally not curative because of difficulty in obtaining clear margins. The best results have been obtained using PBT. They (NCI, 2004) also noted that proton use is reserved for the treatment of cancers that are difficult or dangerous to treat with surgery, such as a chondrosarcoma at the base of the skull. PBT may also be used in combination with other forms of radiation therapy.

In their bone cancer guide, the American Cancer Society (2009a) stated PBT "has been found to be very helpful in treating skull base chondrosarcomas and chordomas". In the treatment of chordomas, PBT may be used alone or with intensity-modulated radiation therapy. PBT has been found to work well in the treatment of chondrosarcomas in the skull because they are resistant to radiation and high doses are required.

Craniopharyngiomas: Complete surgical excision while preserving surrounding structures is the initial treatment for craniopharyngiomas. When the tumor cannot be completely removed, radiation therapy may be offered. PBT has been proposed as superior over conventional radiation, due to the damage that conventional radiation may cause to the hypothalamus and optic pathway. Craniopharyngiomas have a high recurrence rate. Following total removal, recurrence ranges from 30–100% and following partial removal, 30–100%. Retrospective reviews have reported achievement of local control of craniopharyngiomas and absence of acute side effects following PBT (Luu, et al., 2006). A 10-year survival rate of 72% following PBT has also been reported (Fitzek, et al., 2006). Dose-related outcomes of radiotherapy for craniopharyngiomas have reported lower recurrence rates (e.g., 13% versus 33%) and improved local control rates (34% vs. 100%) with higher dose radiation (> 54-69 Gray [Gy]) (e.g., PBT) compared to lower radiotherapy dosage (< 57 Gy) (e.g., conventional radiation therapy).

Glioma: The treatment outcome for patients with malignant glioma remains largely unsatisfactory, most tumors progress, and ultimate cure remains elusive. Surgery followed by conventional radiotherapy to doses of 45–60 Gy with high-energy photons leads to five-year survival of 50%–60% for Grade 2 lesions, and 20%–40% for Grade 3 lesions. Outcomes of case series and retrospective reviews have included five-year survival rates of 71% (Fitzek, et al., 2001) and improvement or resolution of gliomas following PBT (McAllister, et al., 1997). Better results were noted in patients with lower grade tumors.

Meningioma: Case series have reported four-year local control rates of $87.5 \pm 12\%$, an overall survival rate of $88.9 \pm 11\%$, five-year actuarial local rates of 80%, and clinical stability and/or improvement rates of 89% for 12–155 months following PBT for the treatment of meningiomas (Hug, et al., 2002; Noel, et al., 2002; Vernimmen, et al., 2001; Gudjonsson, et al., 1999).

The National Institute for Health and Clinical Excellence (2006) (United Kingdom) stated that stereotactic radiosurgery may be a useful treatment option for meningiomas but the value of the therapy is still uncertain.

Pituitary Adenoma: Ronson et al. (2006) retrospectively reviewed 47 records of patients with nonmetastatic pituitary adenomas treated with fractionated PBT. Radiologically, 41 patients demonstrated tumor stabilization, 10 had no residual tumor, and three had > 50% reduction in tumor size. Normalized or decreased hormone levels were achieved in 17 patients with functional adenomas, while progression occurred in three patients.

The American Cancer Society (2009b) noted that pituitary tumors are treated by surgery, medications that block hormone secretion of the tumors, or by radiation therapy including PBT. PBT has the advantage of being directly focused on the tumor.

The National Cancer Institute (2008) included stereotactic radiation surgery as a treatment option for patients with recurrent or residual pituitary adenomas, and noted that the technology is under evaluation for the treatment of adrenocorticotrophic hormone-producing tumors and recurrent pituitary tumors.

The International RadioSurgery Association (2004) guideline on stereotactic radiosurgery for patients with pituitary adenoma stated that stereotactic radiosurgery, including PBT, is typically used in combination with surgery but may be used alone in certain situations. Single sessions may be especially useful for patients with advanced age, multiple comorbidities making them a surgical risk, and tumors involving the cavernous sinus.” Subgroups most likely to benefit from stereotactic surgery are “patients with residual or recurrent pituitary adenoma after resection, and patients with small pituitary adenoma without any previous surgery”.

Technology Assessment

The Agency for Healthcare Research and Quality published a 2009 technology report on particle beam radiation therapies for the treatment of cancers including skull base and brain tumors. They noted that there is a proposed advantage of using particle beam therapy, including PBT, where precise radiation targeting is critical in tumors of the skull base and tumors adjacent to the brain and brain stem. The report concluded that studies on charged particle therapy “do not document the circumstances in contemporary treatment strategies in which radiotherapy with charged particles is superior to other modalities. Comparative studies in general, and randomized trials in particular (when feasible) are needed to document the theoretical advantages of charged particle radiotherapy to specific clinical situations”.

In a technology assessment on the use of PBT for the treatment of cancer, the Australia and New Zealand Horizon Scanning Network (2006) stated that PBT “may be of particular benefit” in the treatment of patients with intermediate depth tumors such as those in the head, cancers that are located in difficult or dangerous-to-treat areas, and tumors in locations where “conventional radiotherapy would damage surrounding tissue to an unacceptable level” (e.g., central nervous system and head). PBT “may be ideal for use in the treatment of pediatric patients where the need to avoid secondary tumors is important due to the potentially long life span after radiation treatment when they may develop radiation induced malignancies.

Summary

Evidence in the published peer reviewed scientific literature and professional societies support proton beam therapy for the treatment of intracranial and skull base tumors when radiation therapy is indicated. Studies have reported improved overall survival rates, improved local control rates, and lower recurrence rates following PBT compared to surgical excision and conventional radiation therapy.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT [®] * Codes	Description
77520	Proton treatment delivery; simple, without compensation
77522	Proton treatment delivery; simple, with compensation
77523	Proton treatment delivery, intermediate
77525	Proton treatment delivery, complex

ICD-9-CM Diagnosis Codes	Description
170.0	Malignant neoplasm of bones of skull

191.0 – 191.8	Malignant neoplasm of brain
192.1	Malignant neoplasm of other and unspecified parts of nervous system, cerebral meninges
194.3	Malignant neoplasm of other endocrine glands and related structures, pituitary gland
198.3	Secondary malignant neoplasm of other specified sites, brain
225.0-225.2	Benign neoplasm of brain
227.3	Benign neoplasm of other endocrine glands and related structures, pituitary gland
237.0	Neoplasm of uncertain behavior of endocrine glands and nervous system, pituitary gland
237.5	Neoplasm of uncertain behavior of endocrine glands and nervous system, brain and spinal cord
239.6	Neoplasms of unspecified nature, brain

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	10/15/2008	0468	Proton Beam Therapy for Intracranial and Skull Base Tumors

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