Claims Eval

Notice of Independent Review Decision

DATE: October 9, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Proton Beam Radiation Therapy (PBRT)

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

American Board of Internal Medicine
Certified in Medical Oncology

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

☐ Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- 6-22-13 CT of the head to mid thigh
- 7-9-13, office visit
- 7-25-13, office visit
- 7-25-13 CT of soft tissue neck with contrast
- 8-5-13 Lab work performed

- 9-3-13, Letter of Medical Necessity
- 9-10-13, Letter
- 9-24-13, Medical Review
- 9-27-13 Letter
- BCBS Plan
- Proton Beam articles
- Lomalindahealth. What's Proton Therapy? [Video file]. Retrieved from http://www.youtube.com/watch?v=iEKqv8q16rw&sns=em

PATIENT CLINICAL HISTORY [SUMMARY]:

6-22-13 CT of the head to mid thigh, showed there is a primary lesion of the posterior tongue extending from right side the left side and inferior to the hypopharynx as quantified above. There is extensive metastatic cervical adenopathy at all levels as quantified above. There is no ascent metastonis to chest, abdomen, or skeletal structures.

7-9-13, the patient presents with BOT cancer with bilateral neck nodes diagnosed 6-13. He had biopsy of a right neck node and a PET scan. Tumor is HPV+, poorly differentiated. T4N2cM0 SCCA of the ROT, HPV+. He presented with a sore throat x 8 weeks. He noted a neck mass x 4 weeks. He has had a voice change for 6 weeks. Swallowing is painful, right ear pain and right neck pain. Weight loss of 15lbs because of decreased intake. Breathing abnormal. Snoring more. Has more fatigue. Assessment: T4N2cMCI SCCA of the BOT, HPV+, good performance status, no comorbidity. Plan: Recommend induction chemotherapy with Taxol-Carboplatin followed by CT-RT. Goal of treatment is cure with high likelihood. Advised to see dentist. Will arrange visit with radiation oncologist. He discussed rationale, details, side effects and PEG tube with him. He will call once he has made up his mind.

7-25-13, the patient presents with T4a N2c squamous cell carcinoma of the base of tongue that the evaluator is seeing in consultation at the request of his otolaryngologist, for evaluation of radiation therapy. The patient is a male who developed a sore throat approximately 2 months ago. He developed a right neck mass approximately 1 month ago, was seen by his otolaryngologist, who attempted an FNA, however, the samples are insufficient. Further workup including a CT scan performed on 6-11-13 revealed a right base of tongue mass 3.2 x 3 x 2.4 cm crossing midline extending into the right pharyngeal wall. Additional workup including a PET scan on 6-22-13 due to the bilateral cervical adenopathy with the base of tongue mass. He underwent an excisional biopsy on 6-23-13 and right level 5 lymph node was biopsied showing poorly differentiated squamous cell carcinoma, HPV and P16 positive. Pathology reviewed here confirming ECE. He comes for further evaluation and treatment recommendations. Impression: The patient is a male with T4a N2c M0 squamous cell carcinoma of the base of tongue. The evaluator does think he is a good candidate for definitive chemoradiation therapy with induction chemotherapy as initial portion of his treatment and with concurrent chemoradiation therapy with consideration of a proton therapy due to disease from the base of skull with retropharyngeal nodes

requiring pinpoint radiation therapy. The evaluator has discussed his case in Multidisciplinary Conference and the recommendation was induction chemotherapy followed by concurrent chemoradiation therapy to improve his local control and survival. The risks and benefits of radiation therapy with induction and concurrent were discussed with the patient in detail and all questions were answered to his satisfaction. Plan: The evaluator will discuss for consideration of induction chemotherapy and he will see him back after his second cycle and evaluate his response with consideration of radiation therapy alone or concurrent chemoradiation therapy with proton therapy based on his response to treatment.

7-25-13 CT of soft tissue neck with contrast showed the patient has a very advanced oropharyngeal malignancy with separate components that may be contiguous mucosally but which very heavily involve the right tongue base and extend inferiorly from the left vallecula. The staging is T4a N2c.

8-5-13 Lab work performed.

9-3-13, the evaluator noted that this Letter of Medical Necessity is presented on behalf of. We are requesting certification of CT simulation and 33 treatments of proton radiation therapy for a diagnosis of Stage T4aN2cM0 squamous cell carcinoma of the base of tongue. All relevant clinical information has been reviewed and this patient is meeting eligibility criteria for treatment with proton beam therapy. Radiotherapy is an accepted plan of treatment for tongue cancer. Radiotherapy employing proton beam instead of photons is able to provide the optimum dose to the targeted area without causing potentially serious normal tissue complications including the brain stem and spinal cord, mucosal surfaces of the oral cavity and the oropharynx, cochlea and parotid gland to minimize acute and chronic xerostomia. Consideration of proton therapy would be appropriate to minimize the risk of morbidity and the risk of developing secondary malignancies. is well recognized as a center of excellence for cancer treatment, patient care and research. Our positive outcomes are based on our years of experience and the treatment of cancer and its associated complications.

9-10-13, the evaluator has reviewed the medical documentation submitted by your office regarding the medical necessity (MN) of proton beam radiation therapy for your patient. Our medical policy THE801.023 Charged Particle (Proton or Helium Ion) Radiation Therapy considers proton beam radiation therapy to be medically necessary only for the following clinical situations: primary therapy for melanoma of the uveal tract (iris, choroid, or ciliary body), with no evidence of metastasis or extrascleral extension, and with tumors up to 24 mm in largest diameter and 14 mm in height; or chordoma or low-grade (I or 11) chondrosarcoma of the basisphenoid region (skull-base chordoma or chondrosarcoma) or cervical spine without distant metastases; or central nervous system (CNS) lesions including but not limited to, primary or metastatic CNS malignancies or arteriovenous malformations, located near vital structures such as the optic nerve, brain stem or spinal cord; or pituitary tumors; or primary or postoperative therapy for diffuse low-grade astrocytoma; or primary therapy for early localized prostate cancer; or treatment of radiosensitive pediatric tumors (through age

eighteen). All other applications are considered experimental, investigational, and unproven, including, but not limited to, lung cancer, esophageal cancer, or hepatocellular carcinoma. According to the information you submitted, has been diagnosed with squamous cell carcinoma of the base of the tongue. Because he does not meet the criteria in the medical policy, benefits will be unavailable for proton beam radiation therapy.

9-24-13, performed a Medical Review. It was his opinion based on review of the medical records provided, the proposed treatment consisting of 77523 (Proton Beam Therapy) is considered Experimental/Investigational for this diagnosis and clinical findings. During the past few years, proton therapy has emerged as a new treatment modality for several types of cancer with its advantage of physical dose distribution over conventional radiotherapy. However, only a small number of institutions have a proton beam treatment facility. At the present time, there is no published long term clinical outcome evidence of proton beam RT relative to IMRT for head and neck cancer such as the base of tongue cancer as in this member's case. It is, therefore, not possible to draw any conclusions on the benefits of proton beam RT on health outcomes for tonsillar cancer relative to IMRT, which has demonstrated high locoregional control for early stage tonsillar cancer as in this member's case. The emerging technology committee of the American Society of Radiation Oncology (ASTRO) routinely evaluates new modalities in radiotherapy and assesses the published evidence to determine recommendations for the society as a whole. In 2007, a Proton Task Force was assembled to evaluate the state of the art of PBT. This report reflects evidence collected up to 11-09. Data was reviewed for PBT in central nervous system tumors, gastrointestinal malignancies, lung, head and neck, prostate, and pediatric tumors. The emerging technology committee of the American Society of Radiation Oncology (ASTRO) stated that current data do not provide sufficient evidence to recommend PBT in lung cancer, head and neck cancer, GI malignancies, and pediatric non-CNS malignancies.

9-27-13: This is in response to an appeal received on 9-23-13 for the above mentioned member and services. The appeal along with the clinical information submitted has been reviewed by a board certified physician who specializes in Radiology. This physician had no involvement in the initial determination. After careful consideration of the documentation submitted and the clinical circumstances associated with this case, the appeal request has been denied. This decision was based on the following rationale: This is a 59 year old male with stage T4aN2cM0 squamous cell carcinoma of the base of tongue with metastasis to bilateral cervical nodes. The plan is induction chemotherapy followed by concurrent chemo-radiotherapy. The AP is requesting Proton Beam Radiation Therapy (PBRT) to 70 Gy with concurrent chemotherapy. Proton beam RT is requested in order to spare normal tissues such as parotid glands, brain stem, oral cavity, larynx, and cochleae to minimize risks of morbidity. Based on review of the medical records provided, the proposed treatment consisting of 77523 (Proton Beam Therapy) is considered Experimental/Investigational for this diagnosis and clinical findings. During the past few years, proton therapy has emerged as a new treatment modality for several types of cancer with its advantage of physical dose distribution

over conventional radiotherapy. However, only a small number of institutions have a proton beam treatment facility. At the present time, there is no published long term clinical outcome evidence of proton beam RT relative to IMRT for head and neck cancer such as the base of tongue cancer as in this member's case.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

I have reviewed all available clinical information. Based on the records provided, I am aware of no randomized, phase three clinical data supporting the use of proton therapy in this situation. To the best of my knowledge, proton therapy has not been proven to be more effective than standard of care therapy and therefore this treatment modality is not medically necessary.

Relative biological effectiveness (RBE) values for proton beam therapy

Harald Paganetti, Ph.D.
Andrzej Niemierko, Ph.D.
Marek Ancukiewicz, Ph.D.
Leo E Gerweck, Ph.D.
Michael Goitein, Ph.D.
Jay S Loeffler, M.D.
Herman D Suit, M.D. (D.Phil.
Bottom of Form
Purpose: Clinical proton beam therapy has been based on the use of a generic relative biological effectiveness (RBE) of 1.0 or 1.1, since the available evidence has been interpreted as indicating that the magnitude of RBE variation with treatment parameters is small relative to our abilities to determine RBEs. As substantial clinical experience and additional experimental determinations of RBE have accumulated and the number of proton radiation therapy centers is projected to increase, it is appropriate to reassess the rationale for the continued use of a generic RBE and for that RBE to be 1.0–1.1
Results: The published RBE values, using colony formation as the measure of cell survival, from in vitro studies indicate a substantial spread between the diverse cell lines. The average value at mid SOBP (Spread Out Bragg Peak) over all dose levels is ≈1.2, ranging from 0.9 to 2.1. The average RBE value at mid SOBP in vivo is ≈1.1, ranging from 0.7 to 1.6. Overall, both in vitro and in vivo data indicate a statistically significant increase in RBE for lower doses per fraction, which is much smaller for in vivo systems. There is agreement that there is a measurable increase in RBE over the terminal few millimeters of the SOBP, which results in an extension of the bioeffective range of the beam in the range of 1–2 mm. There is no published report to indicate that the RBE of 1.1 is low. However, a substantial proportion of patients treated at ≈2 cobalt Gray equivalent (CGE)/fraction 5 or more years ago were treated by a combination of both proton and photon beams. Were the RBE to be erroneously underestimated by ≈10%, the increase in complication frequency would be quite serious were the complication incidence for the reference treatment ≥3% and the slope of the dose response curves steep, e.g., a γ50 ≈ 4. To exclude ≥1.2 as the correct RBE

for a specific condition or tissue at the 95% confidence limit would require relatively large and multiple assays.

Conclusions:At present, there is too much uncertainty in the RBE value for any human tissue to propose RBE values specific for tissue, dose/fraction, proton energy, etc. The experimental in vivo and clinical data indicate that continued employment of a generic RBE value and for that value to be 1.1 is reasonable. However, there is a local "hot region" over the terminal few millimeters of the SOBP and an extension of the biologically effective range. This needs to be considered in treatment planning, particularly for single field plans or for an end of range in or close to a critical structure. There is a clear need for prospective assessments of normal tissue reactions in proton irradiated patients and determinations of RBE values for several late responding tissues in laboratory animal systems, especially as a function of dose/fraction in the range of 1–4 Gy

Ann Intern Med. 2009 Oct 20;151(8):556-65. Epub 2009 Sep 14.

Systematic review: charged-particle radiation therapy for cancer.

Terasawa T, Dvorak T, Ip S, Raman G, Lau J, Trikalinos TA.

Source

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Abstract

BACKGROUND:

Radiation therapy with charged particles can potentially deliver maximum doses while minimizing irradiation of surrounding tissues, and it may be more effective or less harmful than other forms of radiation therapy.

PURPOSE:

To review evidence about the benefits and harms of charged-particle radiation therapy for patients with cancer.

DATA SOURCES:

MEDLINE (inception to 11 July 2009) was searched for publications in English, German, French, Italian, and Japanese. Web sites of manufacturers, treatment centers, and professional organizations were searched for relevant information.

STUDY SELECTION:

Four reviewers identified studies of any design that described clinical outcomes or adverse events in 10 or more patients with cancer treated with charged-particle radiation therapy.

DATA EXTRACTION:

The 4 reviewers extracted study, patient, and treatment characteristics; clinical outcomes; and adverse events for nonoverlapping sets of articles. A fifth reviewer verified data on comparative studies.

DATA SYNTHESIS:

Currently, 7 centers in the United States have facilities for particle (proton)-beam irradiation, and at least 4 are under construction, each costing between $100 and $225 million. In 243 eligible articles, charged-particle radiation therapy was used alone or in combination with other interventions for common (for example, lung, prostate, or

breast) or uncommon (for example, skull-base tumors or uveal melanomas) types of cancer. Of 243 articles, 185 were single-group retrospective studies. Eight randomized and 9 nonrandomized clinical trials compared treatments with or without charged particles. No comparative study reported statistically significant or important differences in overall or cancer-specific survival or in total serious adverse events.
LIMITATION:
Few studies directly compared treatments with or without particle irradiation.
CONCLUSION:
Evidence on the comparative effectiveness and safety of charged-particle radiation therapy in cancer is needed to assess the benefits, risks, and costs of treatment alternatives.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☐ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION):**
- ☒ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION):**
  - **Relative biological effectiveness (RBE) values for proton beam therapy**
  - **Ann Intern Med. 2009 Oct 20;151(8):556-65.**