

STATE OF MICHIGAN  
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES  
Before the Director of Insurance and Financial Services

In the matter of:

██████████

Petitioner

v

Blue Cross Blue Shield of Michigan

Respondent

File No. 145760-001

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Issued and entered  
this 11<sup>th</sup> day of February 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On January 12, 2015, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

On January 20, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The health care benefits are defined in BCBSM's *Community Blue Group Benefits Certificate SG*. The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM submitted the material on January 29, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its report to the Director on February 3, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner has been diagnosed with Stage III non-small cell lung cancer. His doctor recommended treatment with proton beam therapy and requested coverage from BCBSM. The treatment was to be provided at the ██████████ at the ██████████. BCBSM denied the request for coverage, ruling that proton beam therapy was not medically necessary for treatment of the Petitioner's condition.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination dated October 31, 2014, affirming its denial. The Petitioner now seeks a review of that adverse determination from the Director.

### III. ISSUE

Is proton beam therapy medically necessary for the treatment of the Petitioner's condition?

### IV. ANALYSIS

#### BCBSM's Argument

In its final adverse determination, BCBSM wrote:

A board-certified M.D. in Radiation Oncology reviewed your claim, your appeal, and your health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM) and determined the following:

- We do not consider PBT [proton beam therapy] to be investigational; however, there is insufficient evidence to show that PBT is superior to photon based radiotherapy for lung cancer, and therefore, the treatment does not meet the standard for medical necessity;
- The National Cancer Institute (NCI) letter states that proton therapy is hypothesized to offer improved outcomes, not that improved outcomes have been demonstrated;
- The National Comprehensive Cancer Network (NCCN) guideline stating that proton therapy is an option for lung cancer does not state that it meets the standard for medical necessity;
- Dosimetric comparison do not prove superior outcomes;
- "As Low As Reasonably Achievable (ALARA)" does not apply to selection of a modality which has not been proven to improve outcomes compared to standard of care;
- Nursing magazine article recommending consideration of avoiding critical organs when possible and monitoring patients for late effects is common sense but not relevant to this appeal, please see ALARA above;
- The ASTRO model policy for PBT placed thoracic malignancies in group 2 for which "there is a need for continue clinical evidence development and comparative effectiveness analysis for appropriate use of PBT." Clinical trials are recommended;

- The same article concludes: "However, much more information is needed regarding the safety of hypo fractionated PBT before it can be widely adopted, and long-term follow-up is urgently needed to assess chronic toxicities (those appearing more than 12 months after treatment) and rates of disease control and survival compared with conventionally fractionated regimens and prior studies using photon techniques." and;
- The BC/TX outside reviewer state that the physical properties of proton "...may make PBRT more effective...." Not that PBRT has been shown to be equally or more effective.

### Petitioner's Argument

In a letter dated December 31, 2014, submitted with the request for external review, the Petitioner's physician wrote:

I am requesting Blue Cross Blue Shield of Michigan to take into consideration the medical necessity for the proton therapy rather than blanket statement of health policy since as his radiation oncologist I deemed that the treatment plan of proton beam therapy is medically necessary for [Petitioner] given the patient's prior history of radiation to his thorax in infancy as well as his young age and good performance status. Proton therapy will be the optimal radiation treatment option to minimize the dose to the surrounding normal structures. Second, the history of prior radiation to the chest at his age of 10 months for pneumonia has likely caused the benign thyroid tumor in his 20's that was needed to be removed surgically, thus proton therapy is medically necessary as it will prevent second malignancy related to conventional radiation treatment. Third, the patient had left video-assisted thoracoscopy, multiple wedge resection of upper lobe and resection of pleural nodule, diagnostic bronchoscopy with removal of left main stem bronchus nodule, end bronchial ultrasound and trans bronchial needle aspirate, since it is unclear whether he has a stage IIIA disease or more advanced disease as a result of additional lung nodules that have been noted on CT scan....The plan is to deliver 35 GY in 35 fractions using proton therapy and likely will receive concurrent chemotherapy. Chemo-radiation was recommended by his physicians in Michigan **as he is not surgical candidate with his clinical status**, thus he presented to [REDACTED], and I as his radiation oncologist recommended radiation therapy with proton as the multimodality treatment of his lung cancer.

With all the supporting documents noted above, we are requesting BC/Michigan to reconsider approving [Petitioner's] proton therapy for his life-threatening diagnosis of stage IIIA left upper lobe cancer. Proton therapy has an advantage over conventional photon radiotherapy in attaining local tumor control, and improving survival with reduced toxicities to normal critical structures including cardiac structure, spinal cord, esophagus as well as contralateral lung. It has been

discussed that the potential cumulative toxicities could be increased with the use of photon; however using the best techniques of planning with proton therapy, we would minimize these severe and deadly complications, especially in [Petitioner's] well compromised clinical status....[P]roton therapy is medically necessary for lung cancer due to its significant low dose to the superior vena cava (blood vessel) compared to IMRT.

### Director's Review

BCBSM's *Community Blue* certificate (page 18) provides that medical services are covered services only when they are medically necessary. The certificate (page 155) includes the following definition of medically necessity:

Health care services that a professional provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- In accordance with generally accepted standards of medical practice;
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the member's illness, injury or disease and
- Not primarily for the convenience of the member, professional provider, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that member's illness, injury or disease.

**NOTE** "Generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician or provider society recommendations and the views of physicians or providers practicing in relevant clinical areas and any other relevant factors.

Whether proton beam therapy is medically necessary for treatment of the Petitioner's condition is a medical question that was presented to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is a physician who is board certified in radiation oncology and has been in practice for more than 15 years. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

[T]he use of proton therapy is an accepted radiation technology, which has proven efficacy and tolerability. However...the issue of whether proton affords any benefit over conventional radiation therapy is not settled at this time. There are physical uncertainties about proton depth dose delivery which may make the actual radiation deposition in tissue less conformal than it may appear based upon a treatment plan....Also, the depth of proton delivery is more susceptible to changes in tissue density.

[P]roton therapy is an accepted, safe and effective treatment modality for stage III lung cancer. The most recent National Comprehensive Cancer Network guidelines include proton therapy as a means to deliver conformal radiation, although they do not address specific indications for the use of proton therapy over intensity modulated radiation therapy....These guidelines state that technologies such as "4DCT, IMRT/VMAT, IGRT, motion management, and proton therapy" are appropriate "when needed to deliver curative RT safely."...[T]hese guidelines do not specify that proton therapy should be used in lieu of other modalities, but rather acknowledge proton therapy as an alternative to be considered. The physician consultant also noted that the most recent American Society for Therapeutic Radiology and Oncology (ASTRO) model policy acknowledges the need for proton therapy when strongly justified by a dosimetric rationale such as specific dose-volume parameters for target and nearby structures, but that such a dosimetric rationale was not provided in this case. This policy includes generic indications for coverage including: "(1) The target volume is in close proximity to one or more critical structures and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s). (2) A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid excessive dose 'hot spot' within the treated volume to lessen the risk of excessive early or late normal tissue toxicity. (3) A photon-based technique would increase the probability of clinically meaningful normal tissue toxicity by exceeding an integral dose-based metric associated with toxicity. (4) The same or immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue."

[W]hile reirradiation can be a justification for proton therapy, the information provided for review did not include any dosimetric rationale to support the use of proton therapy for this member. Reirradiation can be readily achieved with intensity modulated radiation therapy or other photon based techniques....[W]hile reirradiation can be risky, the risk is dependent on the prior dose, prior treatment volume fields, time interval between radiation courses and cumulative dose. The member medical records from the previous radiation treatment as an infant were not provided. However...the dose used in radiation treatment for pneumonia for a 10 month-old infant would have likely been quite low.

[T]he information submitted for review does not adequately document using quantifiable dosimetric measurements that an intensity modulated radiation therapy or 3D conformal plan would be unacceptable or that a proton plan would be superior. The appeal letter from the member's radiation oncologist shows a comparison of an intensity modulated radiation therapy (IMRT) plan with a proton therapy plan, which depicts unnecessary radiation with IMRT in what seems to be an "example patient", but does not provide specific dosimetric data for this member and does not document dose metrics for the heart, normal lung, spinal cord, brachial plexis and esophagus for this member or show that an IMRT or conventional 3D conformal plan would be unacceptable for him with respect to commonly accepted tissue tolerances....[T]his letter questions whether the member may have more advanced stage disease "as a result of additional lung nodules that have been noted on CT scan."...[I]f the member were to have stage IV disease, any radiation would be palliative in nature.

[T]he information provided for review does not adequately document that IMRT would yield an unacceptable plan for the member with respect to doses delivered to critical structures, such as the spinal cord, lung, heart, esophagus and brachial plexus....[P]roton therapy will almost always reduce dose to surrounding tissue. However...stating that proton therapy will reduce the dose to some normal tissue does not necessarily demonstrate that it is superior to IMRT as the reduction should be clinically meaningful and reduce toxicity risks in a clinically meaningful manner.

Pursuant to the information set forth above and available documentation...proton beam therapy is not medically necessary for treatment of the member's condition. [Citations omitted]

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse determination, the Director must cite "the principal reason or reasons why the [Director] did not follow the assigned independent review organization's recommendation." MCL 550.1911 (16)(b). The IRO's analysis is based on extensive experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that proton beam therapy is not medically necessary for the treatment of the Petitioner's condition and is therefore not a benefit under the terms of the certificate.

**V. ORDER**

The Director upholds BCBSM's final adverse determination of October 31, 2014. BCBSM is not required to provide coverage for the Petitioner's proton beam therapy.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than 60 days from the date of this order in the circuit court for the Michigan county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Annette E. Flood  
Director

For the Director:



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Randall S. Gregg  
Special Deputy Director