STATE OF MICHIGAN

DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES

Before the Director of Insurance and Financial Services

In the matter of:

[redacted],

Petitioner,

v **File No. 154251-001**

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 27th day of June 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

[redacted] (Petitioner) was denied coverage for proton beam therapy by her health insurer, Blue Cross Blue Shield of Michigan (BCBSM).

On June 21, 2016, [redacted], M.D., the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an expedited external review of that denial under the Patient's Right to Independent Review Act. MCL 550.1913. On June 21, 2016, after a preliminary review of the material submitted, the Director accepted the request for an expedited external review

The Petitioner receives group health care coverage through a plan that is underwritten by BCBSM. The Director immediately notified BCBSM of the expedited external review and asked for the information it used to make its final adverse determination. BCBSM responded on June 21, 2016.

This case was assigned to an independent review organization which completed its review and sent its recommendation to the Department of Insurance and Financial Services on June 23, 2016.

II. Factual Background

The Petitioner's health care benefits are described in BCBSM's *Simply Blue HSA Group Benefits Certificate with Prescription Drugs SG* (the certificate).

The Petitioner was diagnosed with "ductal carcinoma in situ" (DCIS) of the right breast. On March 29, 2016, she had surgery and it was recommended that she undergo adjuvant radiation therapy. The Petitioner had concerns about photon radiation therapy so her physician asked BCBSM to cover treatments using proton beam radiation therapy

BCBSM denied the request, saying that proton beam therapy was not medically necessary to treat the Petitioner's condition. The Petitioner's authorized representative was granted an expedited appeal of the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated June 16, 2016, affirming its denial. The Petitioner now seeks an expedited review of that final adverse determination from the Director.

III. Issue

Is proton beam radiation therapy medically necessary to treat the Petitioner's condition?

IV. Analysis

BCBSM's Argument

In its final adverse determination, BCBSM's representative explained its denial to Petitioner's representative:

> A medical consultant, board-certified M.D. in Radiation Oncology and a Grievance and Appeals Coordinator for Blue Cross Blue Shield of Michigan (BCBSM) reviewed the appeal request, [the Petitioner's] health care plan benefits, and the medical documentation submitted with the request. Based on that review, it was determined that Proton Beam Therapy is not medically necessary for [the Petitioner's] medical condition. Thus, prior authorization is not approved.
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> As mentioned above, a board-certified M.D. in Radiation Oncology reviewed the medical documentation that was supplied. Based on that review the following was determined:
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>> The request does not meet the AIM Clinical Appropriateness Guideline for Proton Beam Radiation Therapy because Proton Beam Radiation Therapy (PBT) is not medically necessary for treatment of right sided breast cancer.

> For the purposes of the appeal, I reviewed other evidence beyond the AIM Clinical Appropriateness Guidelines to assess the medical necessity of this request for proton therapy to treat lung cancer.
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> The requesting physician's office has cited comparative dosimetry articles suggesting that treatment with protons may theoretically reduce the risk of both late cardiac toxicity and the risk of second cancers; however, there was no patient specific dose comparisons included. Finally, the appeal request includes a copy of the ASTRO Model Policy for Proton Beam Therapy. That policy clearly states that the use of proton beam therapy is not typically supported in cases "where PBT does not offer an advantage over photon-based therapies that otherwise deliver good clinical outcomes and low toxicity." There is widespread agreement that current, non-PBT techniques for the treatment of breast cancer deliver excellent long term outcomes with low toxicity. Therefore, proton therapy is not supported for this indication.
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> In conclusion, there is consensus within the specialty of radiation oncology that the role of proton therapy in the treatment of right sided breast cancer lacks high quality comparative evidence, offers no clear benefit over photon based radiotherapy and is much more costly. For those reasons, I find that proton therapy is not medically necessary in the treatment of right sided breast cancer in this case.

Therefore, because the use of Proton Beam Therapy is not medically necessary to treat [Petitioner's] condition, we are unable to approve prior authorization.

Petitioner's Argument

In a letter dated June 20, 2016, submitted with the external review request, the Petitioner wrote:

> On March 1st [2016] I was diagnosed with High grade DCIS ER, PR negative / High Oncotype grade and I had right sided lumpectomy followed by recommendation to proceed with radiation therapy.
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> Both my initial prior authorization as well as the expedited appeal requests [were] unjustifiably denied by [BCBSM].
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> These are my supporting facts:
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> 1) Very strong family history of lung cancer and solids tumor
> 2) My father died of right lung cancer.
> 3) My father had 6 siblings:
> One of his brothers died of lung cancer and he has never used tobacco.
> 2 cousins have history of cancer one died in her 20's of astrocytoma
> One of his sisters died of brain metastasis, unknown primary.

His mother had lung cancer; she [h]as no history of tobacco use.

4) I have a congenital cardiac condition – mitral valve prolapse.

Genetic analysis shows that this could represent either a familial clustering of cancer within the family or an inherited cancer predisposition syndrome.

Based on my very strong family history of lung cancer I elected to have proton beam therapy rather than photon therapy to avoid lung toxicity.

The appeal reviewer argues that conventional therapy risk is very small but in my case that risk is [unacceptable] high because of strong family history of lung cancer. My decision to elect proton beam therapy is not out of convenience but in trying to avoid future complications.

In a letter dated June 8, 2016, submitted with the request for external review, The Petitioner's physician wrote:

On behalf of [Petitioner], we are submitting our appeal for the denial of her proton therapy, which [BCBSM] considers as not medically necessary for her life-threatening diagnosis of ductal carcinoma in situ of the right breast, high grade, ER / PR negative.

* * *

I am rebutting [the] denial reason as there are medical studies that were published that partial breast irradiation randomized trials or cohort studies that shows that it is far effective and yield same result with conventional whole breast irradiation as well as cosmetic outcome. Thus [BCBSM] should approve accelerated partial breast irradiation (APBI) for [Petitioner's] life-threatening clinical stage Tis (DCIS) ductal carcinoma in situ of the right breast, ER/PR negative.

. . . [The Petitioner] is a 54-year-old female who presents with screen detected ductal carcinoma in situ. She had a normal screening in 2013 had skipped 2014 and 2015 and on 2016 screening showed a new focus of pleomorphic micro calcifications in the right breast upper outer quadrant. On March 1, she underwent a stereotactic core biopsy, pathology was reviewed at University of Michigan which showed high-grade ductal carcinoma in situ, ER/PR negative. MRI on March 19, 2016 of the breast showed a few residual suspicious calcifications in the right breast and post biopsy marker clip. She underwent a needle localized segmental mastectomy on March 29, 2016 and post-operatively mammogram confirms removal of all suspicious microcalcifications. The pathologic stage is TisN0M0. She is self-referred for evaluation and consideration of radiation therapy treatment options following segmental mastectomy for high-grade ductal carcinoma in situ of the right breast. Given the high grade it would be reasonable for radiation therapy with proton beam therapy

> as proton therapy will offer the best lung sparing of the available treatment options and this should help to minimize her late risk of radiation-induced lung cancer. It should be noted that [the Petitioner] had a strong family history of lung cancer; father and multiple paternal cousins all had lung cancer despite a minimal smoking history. At the time of simulation, it was apparent that tumor bed clips [and] not been placed by her surgeon at the time of lumpectomy. I her radiation oncologist, believe that the tumor bed can be delineated with the assistance of the scar marker, but it is difficult to identify the tumor bed with precise certainty. This finding renders her ineligible for our phase II proton partial breast radiation protocol. However, she remains eligible for our normal tissue toxicity proton study and she was enrolled [on] the study. I[n] light of the challenge and identifying her tumor bed, I have opted to utilized a 2 cm expansion from the visualized tumor bed to delineate the CTV. This should ensure the adequate cover any residual tissue at risk for residual disease and can treat this target volume while still meeting all normal tissue dose constraints.
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> Accelerated partial breast irradiation (APBI) for post-lumpectomy irradiation using several approaches have been endorsed for eligible patients by numerous national cancer societies based on published literature. I am treating [the Petitioner] with (APBI) accelerated partial breast irradiation. <u>Phase III data have demonstrated unacceptably high toxicity with 3D-conformal photon based external beam APBI, so we have reviewed instead the pros and cons of several more localized APBI techniques including using protons or multi-lumen catheters –based techniques to limit dose to the non-target breast</u>. After careful review of technical and other issues in this patient <u>we recommend proton based APBI</u>. Proton APBI eliminates the need to place invasive catheters and allows coverage of more irregular shaped tumor beds. Long term clinical data using proton based APBI have been published from two respected institutions demonstrating excellent local control and cosmesis.
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> If cost is the issue, we have recently demonstrated using Medicare claims that the cost of proton based partial breast irradiation is not in excess of other appropriate techniques and regimens to treat breast cancer. This work has been submitted for publication and the summary of charges is inserted confidentially for your review. Thus Proton based APBI is proven, safe, effective and medically necessary radiation treatment and is excellent value based option for appropriate post-lumpectomy patients who desire and are eligible for partial breast irradiation. It is proven radiation treatment modality for [Petitioner] . . . [Underlining in original.]

The Petitioner's physician provided numerous studies to support her position that accelerated partial breast radiation is proven and effective.

Director's Review

The certificate (p. 16) says, "We pay only for "medically necessary services. . . ." "Medical necessity:" is defined in the certificate (p. 175, under "Medical necessity for payment of services of other providers"):

> Determination by physicians acting for BCBSM, based on criteria and guidelines developed by physicians for BCBSM who are acting for their respective provider type or medical specialty, that:
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> — The covered service is accepted as necessary and appropriate for the patient's condition. It is not mainly for the convenience of the member or physician.
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> — In the case of diagnostic testing, the results are essential to and are used in the diagnosis or management of the patient's condition.

The question of whether proton beam therapy is medically necessary to treat the Petitioner's condition was presented to an independent review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

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

> **Recommended Decision:**
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> The MAXIMUS physician consultant determined that proton beam therapy is not medically necessary for treatment of the member's condition.
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> **Rationale**:
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> A proton is the charged nucleus of a hydrogen atom (hydrogen atom minus an electron). Charged particles (such as protons and carbon) can be used to deliver therapeutic radiation. "Standard radiation" is delivered with a linear accelerator (LINAC), which delivers photon therapy (akin to high energy light), while protons (and other charged particles) are generated from a cyclotron. The difference between proton and photon irradiation is that the protons (or charged particles) stop abruptly in the tissue (Bragg peak) so there is less exit dose through normal tissue. The use of proton therapy is an accepted radiation technology, which has proven efficacy and tolerability. Certain conditions, such as base of skull chordomas and chondrosarcomas and pediatric central nervous system malignancies, are probably best treated with proton therapy, due to the sharp dose fall off, allowing high dose delivery to the tumor, while relatively sparing the neighboring normal tissue.

The MAXIMUS physician consultant explained that whether or not proton therapy (in general) affords any benefit over conventional radiation therapy is a heated issue, with quite disparate opinions among experts in the field. Certainly proton therapy is more expensive than photon therapy, which is the root of the disagreement of experts. The physician consultant noted that most (or all) radiation oncologists believe that proton therapy has a role in the treatment of some cancer patients. The consultant indicated that proton therapy is an accepted, safe and effective radiation treatment modality, and there are studies which describe it use in breast cancer.

The physician consultant explained that with proton therapy, 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 the treatment plan. The consultant indicated that depth "range uncertainties" (a unique dosimetric consideration with proton therapy), and the fact that the relative biologic effectiveness of a proton beam increases with the depth, must be considered.

The consultant noted that some assert that that proton therapy could lower the risk of second, radiation-associated, malignancies. The consultant also noted that intensity modulated radiation therapy (IMRT) does result in a greater deposition of low dose to normal tissue, which theoretically increases the risk of second malignancies, though this is controversial. The physician consultant indicated that although proton therapy reduces the low dose deposition, proton therapy results in a greater dose rate and appreciable more neutron exposure (compared to essentially none with IMRT using 6 MV photons), and thus the benefit of protons over IMRT in reducing radiation-associated malignancies is controversial. In a study examining dose delivered to a phantom (i.e. model of a patient), the authors concluded that the "estimated secondary cancer risk using scattering mode in proton therapy is either significantly lower than the cases in IMRT treatment or, at least, does not exceed the risk induced by conventional IMRT." The consultant explained that whether radiation specifically increases risks of second malignancies in patients with a family history of cancer, and whether proton therapy can reduce risk is not well characterized or understood.

The physician consultant explained that while small studies have demonstrated the ability of proton therapy to reduce lung and cardiac dose exposure for left breast cancer, which this member does not have, it is not clear if such reductions are clinically meaningful for proton therapy to be recommended for general use. Many other technologies allow for reduction in normal tissue dosing, including IMRT, prone breast radiation, motion management (breath hold, gating, tracking/monitoring). The consultant indicated that when treating patients with complex target volumes and/or when needing to treat internal mammary, supraclavicular and axillary nodes, proton therapy may yield a better dose distri-

> bution, but neither situation applies for this case. The physician consultant explained that there is nothing in the case file that credibly argues that other radiation techniques would be unacceptable and/or that proton therapy would yield a clinically meaningful advantage for this member.
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> While not directly at issue in this case, the consultant noted that the use of partial breast radiation would be somewhat controversial for this patient. Experts in the field published an ASTRO consensus statement about partial breast radiation, acknowledging that it is becoming standard practice in the community for select cases, despite the paucity of Phase III data, specifically women with low risk of recurrence: age greater than 60, small (less than 2 cm) tumor, T1N0, unifocal breast cancer with negative margins, with surgical cavity adequate distance from skin and chest wall. Patients with age 50-59 fall within the ASTRO consensus statement's "Cautionary group" in which the treatment of women with any of those criteria "should invoke caution and concern when considering APBI." Additional factors for cautionary use of APBI include pure DCIS, ER negative, tumor size 2.1-3 cm, lobular cancer, EIC, close margins, limited / focal LVSI. Patients age less than 50 and/or with more advanced cancer fall within the "unsuitable" group. So this member, whose age is less than 60 and who has DCIS would fall into the "Cautionary group".
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> Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that proton beam therapy is not medically necessary for treatment of the member's condition. [References 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 June 16, 2016.

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.

Patrick M. McPharlin
Director

For the Director:

Randall S. Gregg
Special Deputy Director