

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

**In the matter of:**

██████████

**Petitioner,**

v

**File No. 149123-001**

**Blue Care Network of Michigan,**

**Respondent.**

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

**ORDER**

**I. PROCEDURAL BACKGROUND**

██████████ (Petitioner) was denied coverage for a form of radiation therapy by his health plan. On August 3, 2015, ██████████ the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits through an individual plan from Blue Care Network of Michigan (BCN), a health maintenance organization. The Director notified BCN of the external review request and asked for the information it used to make its final adverse determination. BCN provided its initial response on August 4, 2015. After a preliminary review of the material submitted, the Director accepted the request on August 10, 2015.

The case involves medical issues so it was assigned to an independent review organization (IRO). The IRO submitted its recommendation to the Director on September 2, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are defined in the *Blue Care Network Certificate of Coverage for Individuals* (the certificate).<sup>1</sup>

The Petitioner was diagnosed with prostate cancer. To treat the condition, his physician

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<sup>1</sup> Dated January 1, 2015.

prescribed stereotactic body radiation therapy (SBRT) using the CyberKnife system and asked BCN to cover it.

BCN denied the request, saying the therapy was experimental or investigational for the Petitioner's condition and therefore not a covered benefit. The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process BCN issued a final adverse determination dated June 4, 2015, affirming its decision. The Petitioner now seeks a review of that final adverse determination from the Director.

### III. ISSUE

Is the proposed SBRT with CyberKnife system experimental or investigational in the treatment of the Petitioner's condition?

### IV. ANALYSIS

#### Petitioner's Argument

In a July 31, 2015, letter submitted with the external review request, the Petitioner's authorized representative said:

I represent [the Petitioner] who has been denied coverage by [BCN] for [SBRT] for multiple lesions on his prostate. He has been diagnosed with prostate cancer. The necessary procedure would be performed by a device called "Cyberknife" which Blue Cross has deemed experimental and denied coverage on that basis. ... Objective proofs demonstrate that the Cyperknife treatment option is not experimental and in fact, offers several advantages over alternative treatment including surgery.

\* \* \*

[The Petitioner] noted in his appeal that the Food and Drug Administration . . . approved R-SBRT for treatment of cancer anywhere on the body. The American Society for Therapeutic Radiation Oncology (ASTRO), the national authority on radiation oncology coverage policies, updated their Model Policy on R-SBRT in the Spring of 2013, stating that SBRT was a viable treatment option for prostate cancer. The Blue Cross Blue Shield Association relies on ASTRO for guidance on which radiation therapy services should be allowed for each type of cancer.

\* \* \*

In addition, in December 2013, the National Comprehensive Cancer Network added SBRT to its guidelines for treatment of low-to-intermediate risk prostate cancer. This is the level of risk that my client had as of his last testing in November 2014.

\* \* \*

The accuracy of SBRT allows clinicians to reduce treatment margins and maximally spare critical normal tissue (including but not limited to the rectum, bladder, urethra, and penile bulb) from the high-dose treatment field. The effects are reduced damage of surrounding tissue, and use of a catheter is not necessary. Other types of radiation are longer term in their side effects for urinary incontinence, bowel dysfunction, and sexual impotence.

### BCN's Argument

In its final adverse determination, BCN informed the Petitioner of its decision:

The [grievance] Panel, which consisted of an M.D., who is board certified in pediatric medicine, and the director of customer services, reviewed your request for [SBRT], and upheld the previous denial. We based our decision on the enclosed BCBSM/BCN Medical Policy titled "Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy" which states this procedure is experimental.

### Director's Review

Radiology services are generally a covered benefit under the certificate (see sections 8.4 and 8.5, pp. 32-33). However, the certificate (p. 59-60) has this exclusion in section 9.4:

Coverage does not include the following services:

\* \* \*

- All facility, ancillary and physician services, including diagnostic tests, related to experimental or investigational procedures.

"Experimental or investigational" is defined in the certificate (p. 56) as:

a service that has not been scientifically demonstrated to be as safe and effective for treatment of the Member's condition as conventional or standard treatment in the United States.

BCN relied on its medical policy title "Stereotactic Radiosurgery and Stereotactic body Radiation Therapy" as the basis for its decision that SBRT to treat prostate cancer is experimental and therefore not covered.

The question of whether the SBRT with the CyberKnife system is experimental for the Petitioner's condition was presented to an independent review organization (IRO) for analysis and a recommendation as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is certified by the American Board of Radiology with a subspecialty in radiation oncology; is published in peer reviewed literature; and is in active practice. The IRO report included the following analysis and recommendation:

**Reviewer's Decision and Principal Reasons for the Decision:**

It is the determination of this reviewer that the SBRT therapy with Cyberknife device is not experimental / investigational for treatment of the enrollee's condition.

**Clinical Rationale for the Decision:**

Multiple single institutional studies have reported on the efficacy and safety of Stereotactic Body Radiation Therapy (SBRT) for early stage prostate cancer. Their studies reported of clinical outcome date up to five (5) years which is equivalent to those of other standard treatment modalities such as Intensity Modulated Radiation Therapy (IMRT) +/- brachytherapy for early stage prostate cancer.

Based on these peer reviewed studies, the American Society for Therapeutic Radiology and Oncology (ASTRO) model policy on SBRT states that while it is necessary to observe patients treated for prostate cancer for extended intervals to gauge the rate of long term (beyond ten years) biochemical control and overall survival, the interim results reported appear at least as good as other forms of radiotherapy administered to patients with equivalent risk levels followed for the same duration post-treatment.

It is stated that ASTRO's opinion is that data supporting the use of SBRT for prostate cancer have matured to a point where SBRT could be considered an appropriate alternative for select patients with low to intermediate risk disease. National Comprehensive Cancer Network (NCCN) practice guideline also includes SBRT as one of treatment recommendations for low and intermediate risk prostate cancer.

Based on the radiation oncology national medical organization, ASTRO's statement and NCCN practice guidelines as well as clinical outcome evidence as published in multiple peer reviewed studies, SBRT is not experimental / investigational and it is medically necessary for the enrollee's intermediate risk prostate cancer.

Food and Drug Administration (FDA) provided clearance for the CyberKnife System to treat tumors in the head, neck and upper spine in 1999 and for treatment of tumors anywhere in the body in 2001. The medical / scientific evidence demonstrates that the expected benefits of the requested health care services are more likely to be beneficial to the enrollee than any available standard health care service.

**Recommendation:**

It is the recommendation of this reviewer that the denial issued by Blue Care Network of Michigan for the SBRT therapy with Cyberknife device be overturned.

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 the SBRT therapy with Cyberknife system is not experimental for the treatment of the Petitioner's condition and is therefore a covered benefit.

#### V. ORDER

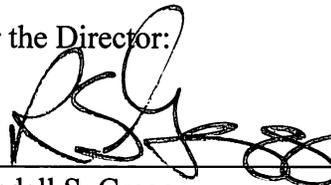
The Director reverses BCN's final adverse determination of June 4, 2015. BCN shall immediately cover the Petitioner's SBRT therapy with Cyberknife device, and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free telephone number (877) 999-6442.

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:



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Randall S. Gregg  
Special Deputy Director