

**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. 150308-001**

**Blue Care Network of Michigan,**

**Respondent.**

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Issued and entered  
this 13<sup>th</sup> day of November 2015  
by Joseph A. Garcia  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

██████████ (Petitioner) was denied coverage for a procedure to help his sleep apnea. His health plan, Blue Care Network of Michigan (BCN), said the procedure was experimental or investigational.

On October 12, 2015, the Petitioner 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 (PRIRA), MCL 550.1901 *et seq.*

The Petitioner receives group health care benefits from BCN, a health maintenance organization. The Director immediately notified BCN of the external review request and asked for the information it used to make its final adverse determination. BCN submitted information on October 14, 2015. After a preliminary review of the material submitted, the Director accepted the request on October 19, 2015. BCN submitted additional documentation on October 21, 2015.

This case involves medical issues so it was assigned to an independent review organization which provided its recommendation to the Director on November 3, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner's health benefits are defined in the *Certificate of Coverage - BCN1 for Large Groups* (the certificate).

The Petitioner has sleep apnea but is unable to use the continuous positive airway pressure (CPAP) machine that was prescribed. His primary care physician referred him to an ear, nose and throat (ENT) specialist for further evaluation as a possible candidate for the Pillar procedure, a treatment that may help people suffering from obstructive sleep apnea whereby tiny implants are inserted into the soft palate.

The ENT specialist agreed that Petitioner was a good candidate for the Pillar procedure and asked BCN to preauthorize it. The cost for the procedure is \$2,500.00. BCN denied authorization, saying it was experimental or investigational and therefore not a benefit.

The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process, BCN affirmed its decision in a final adverse determination dated September 29, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

### III. ISSUE

Was BCN correct when it declined to authorize the Pillar procedure?

### IV. ANALYSIS

#### Petitioner's Argument

The Petitioner explained his grievance on the external review form:

I have been diagnosed with sleep apnea. I am unable to use a CPAP machine because I work 3<sup>rd</sup> shift 4 days a week and my sleep schedule flip-flops every couple days. I was told that I am a good candidate for the Pillar procedure, but was denied coverage from BCN.

#### BCN's Argument

In its final adverse determination, BCN explained its decision to deny coverage procedure:

. . . Our Step Two grievance panel . . . reviewed your request for the Pillar procedure, and upheld the previous denial.

They determined that Blue Care Network (BCN) cannot authorize the service as the requested service is experimental/investigational. The denial is based on our medical policy titled, "Obstructive Sleep Apnea and Snoring - Surgical

Treatment." This enclosed policy states the effectiveness of this treatment has not been established to be equal to or better than traditional therapy.

#### Director's Review

The certificate, in "Section 9.4 Non-Covered Services" (p. 53), has this exclusion:

Coverage does not include the following services:

\* \* \*

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

BCN's medical policy title "Obstructive Sleep Apnea and Snoring – Surgical Treatment" (p. 12) says:

The Pillar Procedure is a trade name for palatal implants. Palatal implants have not been shown effective for the treatment of obstructive sleep apnea and are not covered.

The question of whether the Pillar procedure is experimental or investigational for the treatment of 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 certified by the American Board of Otolaryngology 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 Pillar procedure is experimental / investigational for the treatment of the enrollee's condition.

**Clinical Rationale for the Decision:**

Palatal implants for sleep apnea treatment remain in clinical trials, are unproven ...and are by definition considered experimental investigational.

The standard of care at this time for a patient with mixed sleep apnea remains positive airway pressure therapy, as central apnea does not respond to surgical means of treatment.

Although the Pillar procedure was Food and Drug Administration (FDA) approved for the treatment of mild to moderate obstructive sleep apnea in 2003, the peer reviewed evidence does not demonstrate that the Pillar procedure is likely to be beneficial to this enrollee. In a randomized, double blinded and sham controlled trial of twenty (20) patients with obstructive sleep apnea who underwent palatal implants, there was no difference in outcomes between the implant and the control group, and the Epworth Sleepiness Scale score did not improve significantly. The study was limited by its small size and lack of long term follow up.

Friedman et al concluded in this industry sponsored randomized, blinded, sham controlled study, with success being defined as an apnea-hypopnea index (AHI) reduction of 50% and AHI under twenty (20), that palatal implantation in this study resulted in a successful treatment of only 41%, with no long term follow up.

With a lack of a defined subgroup who might benefit from this procedure, lack of long term follow up, and with a clinical central component to this enrollee's sleep apnea, ac-

ording to the peer reviewed literature, the Pillar procedure is experimental / investigational for this enrollee.

**Recommendation:**

It is the recommendation of this reviewer that the denial issued by Blue Care Network of Michigan for the Pillar procedure be upheld.

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 certificate. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that the Pillar procedure is experimental or investigational for treatment of the Petitioner's condition and therefore is not a covered benefit.

**V. ORDER**

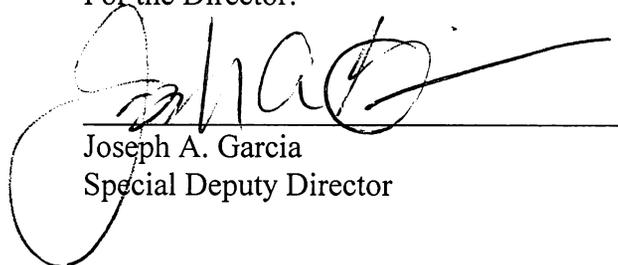
The Director upholds BCN's final adverse determination dated September 29, 2015.

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 sixty 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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Joseph A. Garcia  
Special Deputy Director