

**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. 151870-001**

**Blue Cross Blue Shield of Michigan,**

**Respondent.**

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**Issued and entered**  
**this 11<sup>th</sup> day of April 2016**  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

Respondent Blue Cross Blue Shield of Michigan (BCBSM) denied coverage for the nasal surgery that James Potvin (Petitioner) had on July 20, 2015.

On January 26, 2016, 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, MCL 550.1901 *et seq.* On February 2, 2016, 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 BCBSM. The Director immediately notified BCBSM of the external review request and requested the information it used to make its final adverse determination. BCBSM responded on March 5, 2016.

The medical issues in this case were evaluated by an independent review organization which provided its recommendation to the Director on March 25, 2016.<sup>1</sup>

**II. FACTUAL BACKGROUND**

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

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<sup>1</sup> Additional time was required to allow the Petitioner to obtain medical records needed for the IRO's review.

The Petitioner complained of nasal obstruction and had two to three sinus infections a year. His physician recommended nasal surgery.

On July 20, 2015, the Petitioner had surgery to correct several problems, including asthma, obstructive sleep apnea, snoring, and chronic sinusitis. BCBSM covered part of the surgery but denied coverage for CPT code 31295 (“nasal / sinus endoscopy, surgical; with dilation of maxillary sinus ostium. . .”) saying it was experimental or investigational for the treatment of the Petitioner’s condition.<sup>2</sup> The charge for the procedure was \$7,946.38.

The Petitioner appealed the denial through BCBSM’s internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination dated November 30, 2015, upholding the denial. The Petitioner now seeks review of that final adverse determination from the Director.

### III. ISSUE

Was the Petitioner’s surgery (CPT code 31295) experimental or investigational for treatment of his condition?

### IV. ANALYSIS

#### Petitioner’s Argument

In a January 18, 2016, letter submitted with his request for an external review, the Petitioner wrote:

I am sending in a request for an external review of denied insurance payment for a surgical service. I am enclosing . . . a comprehensive letter from my surgeon detailing the medical necessity of the surgery. He reveals my medical information in this letter complete with a copy of the CAT scan as well as documentation of studies supporting the use of this procedure across the country. . . .

As my doctor has documented in his letter, the surgery stopped me from having to use an expensive CPAP machine for the rest of my life and lessened my reliance on medications. The intervention saved further medical expense and improved the quality of my life except for the medical hardship I am now facing as a result of BCBS denial of payment for the surgical services. . . .

The Petitioner also submitted a letter he received from his surgeon dated January 8, 2016, which explained the need for the surgery:

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<sup>2</sup> BCBSM also rejected related CPT codes 31296 and 30140 as experimental or investigational but they were not specifically mentioned in the final adverse determination.

I first had the opportunity to meet you on 5/25/15. We reviewed the findings of the CT scan demonstrating a slightly deviated, but relatively non-obstructive septum, enlarged inferior turbinates and bilateral maxillary sinusitis with complete opacification on the right. We discussed the importance of reducing your nasal obstruction as it has profound effects on your obstructive sleep apnea. With your relatively low, but abnormal AHI, a surgical procedure may preclude the long term use and expense of a CPAP machine. The plan for the procedure was made after you failed all medical therapy.

We went to the OR for intervention on 07/20/15. I performed bilateral maxillary balloon dilations with irrigation and drainage of the retained mucous. This was in an effort to re-establish mucociliary flow. This procedure was cleared by the USDA in the year 2005 and has been a technology used by surgeons across the country. The majority of insurance companies have accepted this decade long technology as it delivers a consistent, significant and lasting improvement in symptoms. . . .

Finally, reduction of the turbinates in your situation resulted in a significant increase in airflow. This has seemingly obviated the need for additional CPAP therapy. As mentioned above, your highly symptomatic state of nasal airflow obstruction noted in the office greatly exacerbated any obstructive symptoms that you may have experienced.

### BCBSM's Argument

In its final adverse determination to the Petitioner, BCBSM explained its denial of coverage:

. . . After review, I confirmed the denial of payment must be maintained. The service performed, procedure code 31295 . . . has been determined to be experimental / investigational by the BCBSM / Blue Care Network (BCN) Joint Uniform Medical Policy Committee (JUMP). Your health care plan does not cover experimental or investigational services. Therefore, payment cannot be approved for the \$7,946.38 in non-covered charges for these services.

\* \* \*

An investigational status means that the safety and effectiveness of a particular technology has not been definitively determined. An established technology means that the safety and effectiveness have been definitively determined. Investigational medical policies are reviewed regularly to guarantee that the investigational status continues to be supported by the evidence.

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To give your appeal every consideration, a board-certified M.D. in General Surgery reviewed your claim, your appeal, and your health care plan benefits for BCBSM. The medical consultant concluded:

All of the submitted documentation was reviewed. The member is appealing the denial of nasal surgery under procedure code 31295 . . . for a diagnosis of chronic sinusitis. We are unable to approve the payment at this time, as the Blue Cross Blue Shield of Michigan medical policy *Balloon Sinuplasty for Treatment of Chronic Sinusitis* states that balloon sinuplasty for treatment of chronic sinusitis is investigational. It has not been scientifically demonstrated to be as safe and effective as conventional treatment.

I understand your concern regarding the denial of payment for your surgery services. However, BCBSM must administer benefits according to your group's health care plan. Experimental or investigational services are not a benefit and cannot be approved for payment.

#### Director's Review

The certificate (p. 137) excludes coverage for experimental treatment and services related to experimental treatment. Experimental treatment is defined in the certificate (p. 155) as:

Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

To evaluate the question of whether the Petitioner's surgery was experimental or investigational, the Director presented the issue 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 board certified in otolaryngology; a member of the American Academy 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 nasal surgery procedure code 31295 (balloon sinuplasty of the maxillary sinus) and related surgery services performed on July 20, 2015 is considered experimental / investigational for the treatment of the enrollee's condition.

#### **Clinical Rationale for the Decision:**

Balloon ostial dilation was approved by the Food and Drug Administration for surgical treatment of sinusitis in 2005.

\* \* \*

In enrollee correspondence on October 30, 2015, the enrollee states that “surgery was performed to fix several health issues including asthma, obstructive sleep apnea and chronic sinusitis.” There was CT evidence of bilateral maxillary sinusitis with complete right maxillary sinus opacification. According to Hepworth, opacification of a sinus by solid tissue inhibits view and access with a balloon device, and such disease cannot be cleared. It is recommended that the surgeon must consider that the access to these sinuses afforded by dilation of the native ostium would likely be inadequate for extirpation of disease or for maintenance of drainage postoperatively with topical treatment. Maximal medical therapy must first be met prior to the consideration of a surgical alternative and if the enrollee failed maximal medical therapy (which is not documented in the clinicals provided) then functional endoscopic sinus surgery would be considered standard of care as it remains industry standard in the surgical treatment of sinusitis.

Although the peer reviewed literature demonstrates some favorable results in balloon sinuplasty, data is negatively impacted by significant methodological flaws, including small sample size, lack of prospectively selected control group, use of self-reported data, short follow-up, significant losses to follow-up, lack of blinding, and few studies that compare outcomes of balloon sinuplasty compared to functional endoscopic sinus surgery, which is considered the industry standard. Balloon sinus ostial dilation remains in clinical trials in the treatment of sinusitis, is unproven . . . the medical literature is inconclusive in its effectiveness and it is considered by definition to be experimental/investigational. Based upon clinical findings provided, and the peer reviewed literature, balloon ostial dilation is not medically necessary.

**Recommendation:**

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for nasal surgery procedure code 31295 (balloon sinuplasty of the maxillary sinus) and related surgery services performed on July 20, 2015 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 Petitioner’s certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that the surgery the Petitioner had on July 20, 2015 (CPT code 31295), was experimental or investigational and therefore not a covered benefit.<sup>3</sup>

**V. ORDER**

The Director upholds BCBSM's final adverse determination of November 30, 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



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Randall S. Gregg  
Special Deputy Director

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<sup>3</sup> The provider in this case participates with BCBSM. The certificate (p. 120) says that a participating provider may not bill a patient for a service determined by BCBSM to be experimental unless the provider has given the patient an estimate of the cost of the services and the patient has agreed in advance and in writing to receive the service and pay for it.