

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. 152216-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 11th day of April 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On February 16, 2016, ██████████ (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 February 23, 2016, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan that is underwritten by Blue Cross Blue Shield (BCBSM). The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM furnished the information on February 29, 2016.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation on April 1, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in BCBSM's *Community Blue Group Benefits Certificate LG* (the certificate).

The Petitioner has a history of migraine headaches. His plastic surgeon proposed treating his condition with a procedure called "surgical deactivation of headache trigger sites." When a preauthorization request was submitted to BCBSM, it was denied on the basis that the procedure is experimental or investigational.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination dated December 21, 2015, affirming its denial. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Is the proposed surgical deactivation of trigger sites experimental or investigational for the treatment of the Petitioner's condition?

IV. ANALYSIS

Petitioner's Argument

In the request for external review the Petitioner stated:

Chronic Headaches due to nerve compression . . . After years of treatments and tests, the recommendation of surgical deactivation of headache trigger sites was recommended by [my plastic surgeon] of the OSU Wexner Medical Center. Procedure codes 64722 and 64716 per BCBSM denial.

BCBSM's Argument

In its final adverse determination, BCBSM's representative told the Petitioner:

. . . After review, I confirmed the denial must be maintained; this device is considered investigational/experimental.

* * *

To ensure all consideration was given, a board-certified M.D. in Internal Medicine reviewed the submitted documentation and determined the following:

You have headaches that are being treated with various methods, including Botox; surgical treatment has been proposed. This was previously denied by a board-certified surgeon on the basis of Blue Cross Blue Shield of Michigan Association Medical Policy that states surgical deactivation of trigger sites for all headaches, migraine and non-migraine, is experimental/investigational, as its clinical utility has not been established. No new medical justification has been provided. Previous denial of surgery to treat migraine on the basis of Blue Cross Blue Shield of Michigan Association medical policy "Surgical Deactivation of Headache Trigger Sites" is supported and denial upheld. Deny all codes as before.

Director's Review

The certificate (p. 135) excludes coverage for experimental treatment:

Experimental Treatment

Services That Are Not Payable

We do not pay for:

- Experimental treatment. This includes experimental drugs and devices
- Services related to experimental treatment

“Experimental treatment” is defined in the certificate (p. 156): “Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient’s condition as conventional treatment.”

The question of whether surgical deactivation of headache trigger sites is experimental for the treatment of the Petitioner’s condition 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 board certified in neurology, has been in active practice for more than 18 years, and is familiar with the medical management of patients with the Petitioner’s condition. The IRO report contained the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the requested surgical deactivation of trigger sites is experimental / investigational for treatment of the member’s condition.

Rationale:

* * *

The results of the consultant’s review indicate that this case involves a 51 year-old male who has a history of intractable headaches. At issue in this appeal is whether the requested surgical deactivation of trigger sites is experimental/investigational for treatment of the member’s condition.

The member has been treated with a number of preventive medications including amitriptyline, nortriptyline, valproate, beta blockers, Topamax, Cymbalta and verapamil for persistent chronic daily headache. The member was referred to a plastic surgeon for consideration of peripheral nerve decompression surgery after having failed Botox as well.

The plastic surgeon quoted medical literature demonstrating efficacy of multiple decompression surgeries as well as supratrochlear, supraorbital, greater occipital and lesser occipital nerves as well as third occipital nerve and decompression of “trigger points” in support of this request.

The MAXIMUS physician consultant explained that the trials that have involved sham treatment for surgical decompression of cranial peripheral nerves have been small studies and have not been reproduced by different centers. The physician consultant also explained that the data is preliminary at this point. The consultant indicated that the requested procedure is not considered to be a standard of care at this time. The physician consultant also indicated that larger randomized sham studies need to be done to establish

the efficacy of this procedure. One randomized study had a placebo response approaching 60% for sham surgery, which makes the establishment of efficacy more difficult. The consultant explained that trigger point localization is poorly reproducible from examiner to examiner and therefore decompression of trigger points has cannot be established as an effective treatment at this time.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the requested surgical deactivation of trigger sites is experimental / investigational 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 the requested surgical deactivation of trigger sites procedure is not experimental/investigational for treatment of the Petitioner's condition and is therefore a covered benefit under the terms of the certificate.

V. ORDER

The Director upholds BCBSM's final adverse determination of December 21, 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 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

Case File Abstract:

This case concerns a 51 year-old male for whom authorization and coverage for surgical deactivation of trigger sites (CPT codes 64722 and 64716) has been requested. The Health Plan denied this request on the basis that these services are experimental/investigational for treatment of the member's condition.

A review of the record indicates that the member has a history of migraine headaches. Medical records from 4/7/15 to 8/5/15 were included in the case file.

On 8/17/15, the member's plastic surgeon wrote a letter in support of this request. This letter indicated that the member has been suffering from migraine headaches for 41 years. It noted that the member experiences daily constant headaches that start in the right greater than left greater occipital nerve and right lesser occipital nerve region and progress to the bilateral supraorbital/supratrochlear nerve region. It also noted that the member felt pressure in his left ear. It indicated that the member has tried medical treatment with neurologists for the past 41 years, but the pain has not been controlled with multiple classes of medication and was causing significant disability with activities of daily living as well as work. It explained that plastic surgeons have been eliminating or reducing migraine headaches with surgery for the last 14 years and have published peer-reviewed articles about the topic that scientifically demonstrated both the anatomy of these patients as well as the positive clinical outcomes from migraine surgery. It provided information about these studies. It indicated that the member has occipital migraine headaches and possible occipital neuritis due to the compression of the greater and third occipital nerves and would undergo decompression of 6 discrete point of possible compression on each greater occipital nerve, including partial resection of semispinalis capitis muscle, release of the obliquus capitis, exploration, dissection and ablation of the occipital artery at its intersection point with the greater occipital nerve and release of the trapezial tunnel and nuchal fascia. It noted that transfer of subcutaneous flaps to shield the nerves would also be performed. It also noted that depending on the magnitude of the third occipital nerve involvement and the lesser nerve involvement, these nerves may have to be decompressed as well. It indicated that this surgery will benefit the member. It also indicated that the success rate for this surgery ranged from 85 to 92%. Another letter from this plastic surgeon dated 8/17/15 indicated that the member would undergo surgery for deactivation of frontal and temporal headaches through peripheral nerve trigger point decompression. It provided information about this surgery. It noted that the temporal migraine trigger site would be deactivated by neurectomy of the zygomaticotemporal branch of the trigeminal nerve. It also noted that the member also had breathing difficulties, as well as sinus and retrobulbar regular migraine headaches and would undergo septoplasty, turbinectomy, addressment of the concha bullosa and addressment of the spurs/contact points, which would help his retrobulbar headaches. Correspondence from the member's neurologist was also included in the case file.

The request for an external review indicated that the member has chronic headaches due to nerve compression. It also indicated that after years of treatment and tests, surgical deactivation of headache treatment trigger sites was recommended by the member's treating physician. Other correspondence from the member was included in the case file.

Articles regarding surgical treatment of migraine headaches were included in the case file.

The Health Plan indicated that these services are experimental/investigational for treatment of the member's condition. The Health Plan explained that its policy states that surgical deactivation of trigger sites for all headaches, migraine and non-migraine, is experimental/investigational as its clinical utility has not been established. The Health Plan also explained that the member is an adult over 18 years in age. The Health Plan's Certificate of Coverage was included in the case file. The Health Plan's policy regarding surgical deactivation

of headache trigger sites also included in the case file.

Standard of Review:

In rendering its decision, MAXIMUS has interpreted the rights and responsibilities of the parties in accordance with applicable Michigan Law, the Health Plan's contract and applicable coverage guidelines and generally accepted principles guiding the provision of health care.

Recommended Decision:

The MAXIMUS physician consultant determined that the requested surgical deactivation of trigger sites is experimental/investigational for treatment of the member's condition.

Rationale:

The MAXIMUS independent physician consultant, who is familiar with the medical management of patients with the member's condition, has examined the medical record and the arguments presented by the parties.

The results of the consultant's review indicate that this case involves a 51 year-old male who has a history of intractable headaches. At issue in this appeal is whether the requested surgical deactivation of trigger sites is experimental/investigational for treatment of the member's condition.

The member has been treated with a number of preventive medications including amitriptyline, nortriptyline, valproate, beta blockers, Topamax, Cymbalta and verapamil for persistent chronic daily headache. The member was referred to a plastic surgeon for consideration of peripheral nerve decompression surgery after having failed Botox as well. The plastic surgeon quoted medical literature demonstrating efficacy of multiple decompression surgeries as well as supratrochlear, supraorbital, greater occipital and lesser occipital nerves as well as third occipital nerve and decompression of "trigger points" in support of this request.

The MAXIMUS physician consultant explained that the trials that have involved sham treatment for surgical decompression of cranial peripheral nerves have been small studies and have not been reproduced by different centers. The physician consultant also explained that the data is preliminary at this point. The consultant indicated that the requested procedure is not considered to be a standard of care at this time. The physician consultant also indicated that larger randomized sham studies need to be done to establish the efficacy of this procedure.

One randomized study had a placebo response approaching 60% for sham surgery, which makes the establishment of efficacy more difficult (Guyuron B, et al. A placebo-controlled surgical trial of the treatment of migraine headaches. *Plastic & Reconstructive Surgery*. 2009.) The consultant explained that trigger point localization is poorly reproducible from examiner to examiner and therefore decompression of trigger points has cannot be established as an effective treatment at this time.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the requested surgical deactivation of trigger sites is experimental/investigational for treatment of the member's condition. (Ducic I, et al. A systematic review of peripheral nerve interventional treatments for chronic headaches. *Ann Plast Surg*. 2014 Apr;72(4):439-42. Guyuron B, et al. Is migraine surgery ready of prime time? The surgical team's view. *Headache*. 2015 Nov;55(10):1464-73. Lee M, et al. The role of the third occipital nerve in surgical treatment of occipital migraine headaches. *J Plast Reconstr Aesthet Surg*. 2013 Oct;66(10):1335-9. Ashkenazi A, et al. Peripheral nerve blocks and trigger point injections in headache management – a systemic review and suggestions for future research. *Headache*. 2010 Jun;50(6):943-52.)

Sincerely,
MAXIMUS



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