

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. 148917-001-SF

██████████

Plan Sponsor,

and

Blue Cross Blue Shield of Michigan, Plan Administrator,

Respondents.

Issued and entered
this 20th day of August 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a medical procedure by his health plan. On July 22, 2015, ██████████ the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services seeking an external review of that denial under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.*

On July 29, 2015, after a preliminary review of the information submitted, the Director accepted the Petitioner's request.

The Petitioner receives health care benefits through a plan sponsored by ██████████ (the plan), a self-funded governmental health plan subject to Act 495. Blue Cross Blue Shield of Michigan Mutual Insurance Company (BCBSM) administers the plan. The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. The Director received BCBSM's response on August 6, 2015.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

To address the medical issues, the case was assigned to an independent review organization which provided its recommendation to the Director on August 12, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in BCBSM's *Community Blue Group Benefits Certificate ASC*¹ (the certificate).

The Petitioner has gastroesophageal reflux disease (GERD). To treat his condition, his physician asked the plan to cover a surgical procedure called the LINX Reflux Management System (LINX). LINX is a small flexible band of interlinked titanium beads with magnetic cores. The magnetic attraction between the beads helps the lower esophageal sphincter (LES) resist opening to gastric pressures, preventing the acid reflux from entering the esophagus.

BCBSM, acting for the plan, indicated that it would cover a laparoscopic fundoplication, another form of anti-reflux surgery, but denied coverage for the LINX. The Petitioner appealed the denial through the plan's internal grievance process. At the conclusion of that process, BCBSM affirmed the plan's decision in a final adverse determination dated July 16, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for the LINX procedure?

IV. ANALYSIS

BCBSM's Argument

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

... The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that [the LINX] surgical procedure is considered investigational. Investigational services are not a benefit under [the Petitioner's] health care plan. Therefore, prior authorization cannot be approved.

* * *

¹ BCBSM form no. 457F, effective 01/14.

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.

A board-certified M.D. in General Surgery reviewed the claim, the appeal, and the health care plan benefits for [BCBSM] and determined the following:

“All of the documentation was reviewed. The provider is requesting preapproval for placement of a LINX Reflux Management System (a surgically implanted device to help reduce stomach pressure from acid build-up) for a [REDACTED] year-old male member with GERD (gastro esophageal reflux disease) - excess stomach acid occurs and/or, occasionally, stomach contents flow back into the food pipe (esophagus). According to the BCBSM medical policy titled “Magnetic Esophageal Ring to Treat gastro esophageal reflux disease (GERD),” indicates that this service is experimental and/or investigational. The use of this device has not been scientifically shown to improve patient clinical outcomes. Therefore, we are unable to approve procedure code 43289, as it is considered investigational and/or experimental.”

Petitioner’s Argument

Along with the external review request, the Petitioner’s authorized representative submitted a July 1, 2015, appeal letter that had been sent to BCBSM which explained the Petitioner’s argument:

Our understanding of the denial comes from [BCBSM’s] letter dated March 31, 2015. The essence of that correspondence is that anti-reflux surgery using LINX is “experimental” or “investigational” or “unproven.” That decision was reached despite the surgeon furnishing all documentation showing [the Petitioner] is an appropriate candidate for this procedure and that its use is supported by the medical records and peer-reviewed literature:

1. [The Petitioner has] a confirmed diagnosis of GERD defined by abnormal pH testing and suffers continued symptoms despite a maximum medical regimen of PPI’s [proton pump inhibitors]; and
2. The surgeon has determined in this case that LINX is both safe and effective and offers an equal or superior alternative to other forms of anti-reflux surgery because of its reversibility, minimal dissection, keeping the anatomy intact, and avoiding prevalent post-Nissen complications including:

- Difficulty swallowing because the stomach is wrapped too high on the esophagus or is wrapped too tightly
- The esophagus sliding out of the wrapped portion of the stomach so that the valve (lower esophageal sphincter) is no longer supported
- Recurrent heartburn despite having surgery
- Bloating and discomfort because many patients cannot belch or burp
- Excess gas

Perhaps most critical for consideration is that the fundoplication procedure cannot be reversed, and in some cases it may not be possible to relieve the symptoms of these complications, even with a second surgery. Conversely, the option of fundoplication remains open in the event the LINX must be removed.

LINX has a well-established safety and efficacy profile because it is:

Less invasive – Placement of the LINX System does not involve significant alterations to anatomy that may limit future treatment options. With the Nissen fundoplication, the top part of the stomach is wrapped around the lower esophagus to improve the reflux barrier.

Removable – If ever needed, the LINX System can be removed during a laparoscopic procedure similar to the implant procedure. Removal of the device generally leaves the esophagus the same as before the implant and does not preclude a subsequent anti-reflux surgery, if medically necessary.

Well-tolerated – After surgery, patients usually go home the same day or the next day. Patients are able to eat a normal diet after surgery as compared with Nissen fundoplication patients who are restricted to a liquid diet which is advanced over several weeks before eating regular food.

Director's Review

The certificate does not generally cover experimental treatment and has this exclusion (p. 130):

Experimental Treatment

Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment, except as explained under “Clinical Trials (Routine Patient Costs),” “Oncology Clinical Trials” in Section 3 and “Services That Are Payable” below. In addition, we do not pay for administrative costs related to experimental treatment or for research management.

“Experimental treatment” is defined in the certificate (p. 145) as

[t]reatment 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.”

The question of whether the LINX 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 board certified in surgery and has been in practice for more than 15 years. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the LINX procedure is not experimental/ investigational for treatment of the member’s condition.

Rationale:

* * *

The member continues to be symptomatic despite maximal proton pump inhibitor regimens. The member’s surgeon feels that the LINX procedure is the best option for him as it maintains the normal function and morphologic anatomy of the stomach while avoiding the complications of a traditional Nissen fundoplication. The MAXIMUS physician consultant explained that there have been a number of reports that demonstrate the safety and efficacy of the LINX system. One study reported the results of this laparoscopically placed device with demonstrated effectiveness at 1 and 2 year follow-up with no evidence of undue side effects. An earlier article also supported the feasibility of this device. The Society of American Gastrointestinal and Endoscopic Surgeons issued a consensus statement in favor of the LINX procedure being efficacious and safe. The physician consultant indicated that furthermore, recent studies have provided longer term data on the safety and efficacy of the LINX procedure. The Food and Drug Administration (FDA) has approved [for] LINX device. The physician consultant explained that a FDA approval requires both safety and efficacy be demonstrated prior to issuance of such a determination. The Centers for Medicare and Medicaid Services (CMS) issued a HCPCS code for this procedure in 2014. [Citations omitted]

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determines that [the] LINX procedure is not experimental/investigational treatment for the member’s condition.

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 LINX procedure is not experimental or investigational for the Petitioner's condition.

V. ORDER

The Director reverses BCBSM's final adverse determination of July 16, 2015. The plan shall cover the Petitioner's LINX procedure within 60 days of the date of this Order, 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, toll free 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 sixty days from the date of this order in the circuit court for the 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