

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. 154402-001

Blue Care Network of Michigan,

Respondent.

Issued and entered
this 3rd day of August 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a surgical procedure to implant a device called LINX by her health plan, Blue Care Network of Michigan (BCN).

On June 30, 2016, ██████████, 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 group health care benefits through 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 responded on July 1, 2016. The Director reviewed the request and accepted it on July 8, 2016.

Because this case involves a medical issue, it was assigned to an independent review organization, which submitted its analysis and recommendation on July 21, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in the *BCN Certificate of Coverage for Classic Large Groups* (the certificate).

The Petitioner has gastroesophageal reflux disease (GERD) and continued to have symptoms despite a regimen of proton pump inhibitors. To treat her condition, her doctor recommended the surgical implantation of a device called LINX, whose purpose is to prevent stomach acid from entering the esophagus.

BCN denied the Petitioner's request to cover the procedure. 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 June 16, 2016.

The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCN correctly deny coverage for Petitioner's proposed surgery?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination, BCN stated:

After thorough review of the case, the Panel maintained the previous denial. As stated in the medical policy referenced above, the LINX Reflux Management System surgical procedure is experimental / investigational. The effectiveness of this treatment has not been established to be equal to or better than traditional therapy. This procedure is not covered per section 9.4 Non-Covered Services of the member's Classic Large Certificate of Coverage, which states: All facility, ancillary and physician services, including diagnostic tests, related to experimental or investigational procedures.

BCN also based its decision on its medical policy title, "Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)," which includes the following (pp. 2, 4-5):

Magnetic esophageal ring insertion for the treatment of gastroesophageal reflux (GERD) is experimental / investigational. The use of this device has not been scientifically shown to improve patient clinical outcomes.

* * *

A laparoscopically-implanted magnetic esophageal ring is being evaluated for the treatment of GERD. Current evidence on magnetic sphincter augmentation (MSA) consists of 2 retrospective comparative cohort studies along with several case series, including 2 uncontrolled and unblinded manufacturer-sponsored studies that were submitted to the FDA for device approval. These single-arm series are of limited usefulness for determining treatment efficacy and provide no information on the comparative efficacy of this procedure with other GERD treatments. The comparative trials are retrospective and non-randomized, and may be affected by selection bias. In addition, the subjective outcome measures used in these two trials, such as the GERD-HRQL, may be biased due to placebo effects with this study design. The objective measure of esophageal pH shows modest improvement compared to baseline, but this is a physiologic measure with uncertain clinical significance. Dysphagia was common in treated patients, although serious adverse events were less common, and the smaller feasibility study did not identify any serious safety concerns at up to 4 years of follow-up. The FDA has required 4 years of follow-up on the 100 subjects in the pivotal study. Independent assessment of the device by non-industry sources would also allow greater certainty. The evidence at this time is insufficient to permit conclusions concerning the effect of this device on net health outcome. It is considered investigational.

Petitioner's Argument

In an April 10, 2016 letter to BCN that was included with the external review request, the Petitioner's authorized representative wrote:

Our understanding of the denial . . . 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. There is a confirmed diagnosis of GERD defined by abnormal pH testing and suffers continued symptoms despite a maximum medical regimen of PPIs; 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...

* * *

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

To determine whether the requested procedure is experimental or investigational for treatment of the Petitioner's condition, the Director assigned this case to an independent review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act.

The IRO physician reviewer is board certified in surgery and has been in active practice for more than 15 years. The IRO reviewer's 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 has a history of proven gastroesophageal reflux disease with a DeMeester score of 21 via Bravo testing and reflux by endoscopy without Barrett's disease. Proton pump inhibitors have provided some relief over the past 15 to 20 years, but the member's symptoms have worsened over the past 3 years and are not controlled with these medications anymore. The attending physician has chosen the LINX procedure as the most appropriate surgical option for the member.

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, which noted that 85% of patients treated with this procedure are off proton pump inhibitors at 6 years and 90% of these patients had symptom relief without the side effects of fundoplication. The physician consultant indicated that furthermore, recent studies have provided longer term data on the safety and efficacy of the LINX procedure. The consultant also indicated that 5 year outcome results demonstrated a 0% unanticipated adverse event rate and significant efficacy. The Food and Drug Administration (FDA) issued an approval letter for the LINX device. The physician consultant explained that an FDA approval letter is only provided following the submission of controlled clinical trial results that it deems sufficient for the demonstration of safety and efficacy. The consultant noted that the post approval data that the FDA has requested is for monitoring and not to demonstrate safety and efficacy. The Centers for Medicare and Medicaid Services (CMS) issued a HCPCS code for this procedure in 2014. The physician consultant indicated that the LINX procedure is medically necessary for surgical treatment of the member's gastroesophageal reflux disease.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the LINX procedure is not experimental / investigational / unproven 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 IRO's 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. The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that the proposed LINX procedure is not experimental or investigational and is therefore a covered benefit.

V. ORDER

The Director reverses BCN's final adverse determination.

BCN shall immediately cover the Petitioner's LINX procedure. MCL 550.1911(17). BCN shall, within seven days of providing coverage, furnish the Director with proof it 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.

Patrick M. McPharlin
Director

For the Director:



Randall S. Gregg
Special Deputy Director