

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. 154732-001

Blue Care Network of Michigan,
Respondent.

Issued and entered
this 24th day of August 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for the surgical implantation of a device to treat his gastroesophageal reflux disease by his health plan, Blue Care Network of Michigan (BCN).

On July 21, 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 health care benefits under an individual plan 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 27, 2016. The Director preliminarily reviewed the request and accepted it on July 28, 2016.

Because this case involves a medical issue, it was assigned to an independent review organization, which submitted its analysis and recommendation on August 11, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in a *Certificate of Coverage for Individuals* (the certificate) issued by BCN.

The Petitioner has gastroesophageal reflux disease (GERD) and continued to have symptoms despite the use of medications. His physician recommended the surgical

implantation of a device called LINX, whose purpose is to prevent stomach acid from entering the esophagus.

The Petitioner's physician asked BCN to authorize the device, the request was denied. The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process BCN affirmed its decision and issued a final adverse determination on June 21, 2016.

The Petitioner now seeks a review of BCN's final adverse determination from the Director.

III. ISSUE

Did BCN properly deny coverage for Petitioner's proposed LINX surgery?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination to the Petitioner's authorized representative, BCN stated:

Our step two grievance panel ... reviewed your request for approval of the LINX procedure for the [Petitioner] and upheld the previous denial. We based our decision on the procedure is considered experimental and / or investigational and per the member's Blue Care Network (BCN) policy, this is not a covered benefit.

BCN based its decision on its medical policy title, "Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)," that has this statement (p. 2):

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.

Petitioner's Argument

In a July 18, 2016 letter accompanying the request for an external review, the Petitioner's authorized representative wrote:

This communication will serve as [our] response to [BCN's] letter dated June 21, 2016 denying the request for the LINX procedure. We are requesting this denial be overturned. Significant clinical and diagnostic patient specific data in support of medical necessity is included in the attachments within this appeal. You will also find a bibliography [citing] studies from peer-reviewed journals presenting results supporting the safety and effectiveness of the LINX procedure and its long-term outcomes, pursuant to the FDA approval. You will also find

endorsement statements from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the American Society of General Surgeons (ASGS) supporting the use of LINX as an effective treatment for GERD.

* * *

This patient's physician has furnished a treatment plan with a comprehensive history and physical, medical records, and relevant supporting literature that clearly supports the LINX procedure. The LINX procedure was unanimously endorsed by the selected FDA advisory panel and approved by the FDA in 2012 using the indication statement, "The LINX Reflux Management System is a laparoscopic, fundic-sparing anti-reflux procedure indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who are seeking an alternative to continuous acid suppression therapy (i.e. proton pump inhibitors or equivalent) in the management of their GERD." All relevant inclusion criteria have been established with this patient and there are no contraindications in the judgment of the surgeon. As noted in the medical records, this patient continues to have chronic GERD symptoms despite maximum medical therapy for the treatment of reflux.

* * *

It is our contention that there is no basis upon which the insurer can support the claim that the LINX Reflux Management System is not a covered benefit, not medically necessary, or could be construed as experimental or investigational. The LINX Reflux Management System meets all standard criterion used to evaluate whether or not a device is investigational: It is FDA approved; the scientific evidence permits conclusions concerning the effect of the technology on health outcomes; the technology improves the net health outcome of GERD patients; the technology is as beneficial as any established alternatives, and the improvement is attainable outside of the investigational setting.

The Petitioner's authorized representative provided copies of journal articles supporting the efficacy of the LINX system.

Director's Review

The certificate, in section 9.4, "Non-Covered Services" (p. 62), says:

We do not pay for

* * *

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

The certificate says, "Experimental or investigational is a service that has not been scientifically demonstrated to be as safe and effective for treatment of the Member's condition as conventional or standard treatment in the United States."

To determine whether the LINX procedure is experimental or investigational for the treatment of Petitioner's condition, the Director presented the case to an independent review organization (IRO) as required by section 11(6) of the 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 active 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 investigational for treatment of the member's condition.

Rationale:

* * *

The member has significant acid reflux, which has been documented by endoscopy and DeMeester scores of 32 and 20 on Bravo pH testing. The member continues to experience symptoms despite maximum medical treatment with proton pump inhibitors (PPI) and H2 blockers. The member's treating physician has chosen the LINX procedure in order to manage his ineffective lower esophageal sphincter, on the basis that it is effective and less invasive with less side effects.

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. The Society of American Gastrointestinal and Endoscopic Surgeons issued a consensus statement in favor of the LINX procedure being efficacious and safe that noted that 85% of patients are off PPIs at 6 years and 90% had symptom relief without the side effects of traditional operations, such as fundoplication. 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 [the] LINX device. The physician consultant explained that an FDA approval letter is only issued following submission of controlled clinical trials that the FDA 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.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the LINX procedure is not experimental/investigational/unproven and is medically necessary for treatment of 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 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. In addition, The Director can discern no reason why the IRO's recommendation should be rejected in the present case.

The Director accepts the IRO's recommendation and finds that the proposed LINX surgical 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.

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