

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. 150217-001

Blue Care Network of Michigan
Respondent

Issued and entered
this 2nd day of November 2015
by **Randall S. Gregg**
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On October 6, 2015, ██████████ of ██████████, authorized representative of ██████████ (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.* After a preliminary review of the material submitted, the Director accepted the request on October 13, 2015. Petitioner's authorized representative provided additional information on October 14, 2015.

The Petitioner receives group health care benefits from Blue Care Network of Michigan (BCN), a health maintenance organization. The benefits are defined in the *BCN Classic for Large Groups* certificate of coverage. The Director notified BCN of the external review request and asked for the information it used to make its final adverse determination. BCN provided its response on October 16, 2015.

This case involves medical issues so it was assigned it to an independent review organization which provided its recommendation to the Director on October 26, 2015.

II. FACTUAL BACKGROUND

The Petitioner has gastroesophageal reflux disease (GERD). His physician asked BCN to provide coverage for a surgical procedure, the LINX anti-reflux system, to treat his condition. The LINX system involves placement of a small band of titanium beads with magnetic cores in the esophagus to prevent reflux from the stomach entering the esophagus. BCN denied the request saying the procedure is experimental/investigational and therefore not a covered benefit.

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 issued October 2, 2015. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Did BCN correctly deny coverage for the proposed LINX procedure?

IV. ANALYSIS

Petitioner's Argument

The Petitioner's authorized representative wrote in an August 24, 2015 letter to BCN filed with the request for an external review:

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....

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....

BCN's Argument

In its final adverse determination, BCN stated that its decision was based on the terms of the *BCN Classic for Large Groups* certificate of coverage and its medical policy "Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)." According to BCN:

The use of this device has not been scientifically shown to improve patient clinical outcomes. 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.

Director's Review

The certificate (9.4) excludes coverage for services that are experimental or investigational. The question of whether the LINX procedure is experimental or investigational for the treatment of the

Petitioner's condition was presented to an independent medical review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO reviewer is a physician in active practice certified by the American Board of Surgery, is a member of the American Society for Metabolic and Bariatric Surgery, and is published in peer reviewed medical literature; and is in active practice. The IRO report included the following analysis and recommendation:

Standard of care treatment options for a patient with the enrollee's clinical circumstances include ongoing medicinal treatment, laparoscopic Nissen fundoplication, transoral incisionless fundoplication (TIF), and the LINX magnetic sphincter augmentation (MSA) procedure. The body of published literature regarding LINX procedure is expanding with data supporting the efficacy and safety of MSA.

* * *

Based on the published data regarding the LINX procedure, this treatment is not investigational/experimental for a patient with this circumstance. The LINX procedure is a minimally invasive procedure for the treatment of GERD and the recently published body of literature includes conclusions of ongoing clinical trials that support the long-term safety and efficacy of this procedure. LINX is United States Food and Drug Administration (FDA) approved and is in accordance with generally accepted professional medical standards as being safe and effective for the treatment of GERD as is documented to exist in this case. LINX is not subject to review and approval by any institutional review board for the proposed use. LINX is not the subject of an ongoing clinical trial that meets the definition of a Phase 1, 2, 3 clinical trial set forth in the FDA regulations. Finally, there is sufficient long-term data to support that this therapy is as efficacious as the established alternative (laparoscopic fundoplication).

* * *

The documentation submitted for review supports that LINX is a proven effective and safe therapy for the condition of GERD as exists in this case. LINX is clinically appropriate for the treatment of GERD for this enrollee. It is not for the convenience of the enrollee or provider. The enrollee has symptoms of chronic GERD. The symptoms date to at least 2012. At that time, his symptoms were reasonably controlled with PPI medications. However, recently his symptoms have increased prompting re-evaluation. He has been appropriately evaluated with an EGD. The enrollee has proven pathologic esophageal acid exposure based on a pH study, and there is no contraindicating esophageal motor condition based on the motility study. He has been appropriately evaluated with motility and endoscopy studies that confirm normal function, no alternative diagnosis, no hiatal hernia. Finally, the enrollee does not have specific contraindications to implantation of the LINX device, such as scleroderma, suspected or confirmed esophagogastric cancer, prior esophageal or gastric surgery or endoscopic intervention, esophageal motor pathology, symptoms of dysphagia more than once per week, esophageal stricture or gross anatomic abnormalities, esophageal or gastric varices, lactating, pregnant or plan to become pregnant, morbid obesity, or age less than twenty one.

Therefore, based on the status of peer reviewed literature, adequate long-term follow up, specialty surgical society position statement affirmation regarding LINX and FDA approval, the proposed LINX procedure is not experimental/ investigation for the treatment of this enrollee.

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 certificate. MCL 550.1911(15).

The Director can discern no reason why the IRO's recommendation should be rejected in the present case and finds the LINX procedure is not experimental or investigational for treatment of the Petitioner's condition.

V. ORDER

The Director reverses BCN's final adverse determination of October 2, 2015. BCN shall immediately provide coverage for the Petitioner's LINX procedure, 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