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. 154070-001**

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 12th day of July 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

(Petitioner) receives health care benefits from respondent Blue Cross Blue Shield of Michigan (BCBSM). When the Petitioner's physician asked BCBSM to cover a laparoscopy procedure for the esophagus, the request was denied.

On June 9, 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. After a preliminary review of the information submitted, the Director accepted the request on June 16, 2016.

The Petitioner receives health care benefits through an individual plan that is underwritten by 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 responded on June 22, 2016.

The medical issues in this case were evaluated by an independent review organization, which provided its analysis and recommendation to the Director on June 30, 2016.

II. Factual Background

The Petitioner's health care benefits are described in the *Blue Cross Premier Gold Extra Benefits Certificate* (the certificate).

The Petitioner has gastroesophageal reflux disease (GERD). His physician requested prior authorization from BCBSM for procedures to treat his condition. BCBSM agreed to cover a laparoscopic fundoplication but denied coverage for an unlisted laparoscopy procedure and the LINX reflux management system,[1] saying they were investigational and therefore not a benefit.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated April 7, 2016, affirming its denial. The Petitioner now seeks 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:

> ... [A]fter further review, our denial of prior authorization for the unlisted laparoscopy procedure, esophagus (procedure code 43289) and the LINX reflux management system as a magnetic ring (to be reported under procedure code 0392T) is maintained. The Blue Cross Blue Shield of Michigan (BCBCM) and the Blue Care Network (BCN) Joint Uniform Medical Policy Committee (JUMP) has determined that these surgical procedures are considered investigational. Investigational services are not a benefit under your health care plan. Therefore, prior authorization cannot be approved.

* * *

[1] The LINX system 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. Magnetic attraction closes the LES immediately after swallowing, restoring the barrier to reflux. Swallowing forces a temporary break in the magnetic bond, allowing food and liquid to pass normally into the stomach.

A medical consultant, board-certified M.D. in General Surgery reviewed your appeal and your health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM) and determined the following:

> All of the documentation submitted by your provider has been reviewed. Your provider is requesting prior authorization treatment for GERD by usage of the LINX Reflux Management System (procedure code 0392T), prior authorization for an unlisted laparoscopy procedure for the esophagus (procedure code 43289), and prior authorization for performance of a laparoscopic fundoplication (procedure code 43280). The overall treatment is approved (procedure code 43280), however, we are unable to approve the use of the LINX system (procedure code 0392T) associated with procedure code 43289, as the BCBSM Medical Policy titled "Magnetic Esophageal Ring for Treatment of Gastroesophageal Reflux Disease," considers this procedure investigational and/or experimental. Approve 43280, deny 43289 / 0392T.

Petitioner's Argument

In a June 2, 2016, letter included with the external review request, the Petitioner's authorized representative wrote in part:

> Relevant Clinical Information
>
> 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. All relevant inclusion criteria has 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.
>
> This patient has a long lasting history of GERD. Included in the attached patient's medical records is a list of the day-to-day PPI's taken by the patient. Use of PPI's do not provide relief. This patient's consistent and prolonged exposure to chronic acid due to uncontrolled GERD presents the possibility of progression to Barrett's esophagus, which is considered a premalignant condition to esophageal adenocarcinoma. There is peer-reviewed literature that has dated back five (5) years supporting the use and efficacy of the LINX procedure to effectively control GERD. Alternate surgical procedures like Nissen fundoplication procedure will expose this

> patient to more invasive surgery, which the insurer is willing to cover by approving Nissen fundoplication. The LINX procedure generally requires a 1-day hospital stay, but in many cases can be performed as an outpatient procedure. Please reconsider this unwarranted denial and overturn the decision to deny the LINX procedure. It is both medically necessary and beneficial to this patient's health, and overall quality of life.

The Petitioner's authorized representative also included medical records, several medical literature articles, and approval documents from the Department of Health and Human Services for the LINX system.

Director's Review

The Petitioner's certificate (p. 146) excludes coverage for investigational medical services:

> Services That Are Not Payable
>
> We do not pay for:
>
> - Experimental treatment. This includes experimental drugs and devices
> - Services related to experimental treatment

The certificate (p. 167) defines experimental treatment 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."

To help answer the question of whether anti-reflux surgery using the LINX reflux management system is investigational for the treatment of the Petitioner condition, the Director presented the issue 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, has been in active practice for more than 15 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

> **Recommended Decision:**
>
> The MAXIMUS physician consultant determined that the LINX procedure is not experimental / investigational / unproven for treatment of the

member's condition.

Rationale:

* * *

The member has symptoms of reflux with a reflux score of 10. Bravo pH testing derived Demeester scores of 27 and 12 for a combined two day score of 21. An EGD did not show evidence of reflux or hiatal hernia. The member is on up to 80mg of Nexium daily without control of his symptoms. The member's physician feels that he has failed all medical options. The attending physician has elected to perform the LINX procedure as the surgical method of treatment for the member's condition.

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 [the] 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 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 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, finds the anti-reflux surgery with laparoscopic placement of the LINX system is not experimental for the Petitioner's condition and is therefore a covered benefit.

V. ORDER

The Director reverses BCBSM's final adverse determination of April 7, 2016. BCBSM shall immediately cover the Petitioner's anti-reflux surgery including the 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, 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