STATE OF MICHIGAN

DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES

Before the Director of Insurance and Financial Services

In the matter of:

[redacted],
Petitioner,

v **File No. 140782-001**

Blue Cross Blue Shield of Michigan,
Respondent.

Issued and entered
this 20th day of May 2014
by Joseph A. Garcia
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On April 21, 2014, [redacted] authorized representative of [redacted] (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 (PRIRA), MCL 550.1901 *et seq.* After a preliminary review of the material received, the Director accepted the request on April 28, 2014.

The Petitioner receives health care benefits under a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Petitioner's benefits are defined in BCBSM's *Community Blue Group Benefit Certificate* (the certificate). The Director notified BCBSM of the external review request and asked for the information used to make its final adverse determination. The Director received BCBSM's response on May 7, 2014.

This case involves medical issues so the Director assigned it to an independent review organization (IRO) which provided its recommendation to the Director on May 12, 2014.

II. FACTUAL BACKGROUND

The Petitioner has gastroesophageal reflux disease (GERD). His physician requested coverage for a surgical procedure, the LINX Reflux Management System (LINX), to treat his condition. BCBSM denied coverage for the procedure saying it was investigational and therefore not a benefit. The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its decision in a final adverse determination

dated March 27, 2014. The Petitioner now seeks a review of that 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 wrote:

> The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that the LINX Reflux Management System is investigational. Therefore, the denial of preauthorization must be maintained. Investigational services are not a benefit of your contract.
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> The JUMP Committee is comprised of physicians and nurses who perform new technology assessments through the review of the world's medical literature. This review also includes consultation with practicing physicians, specialty physician organizations and other providers as appropriate. After consideration of the medical literature and the input of providers, a medical status is determined; this includes the designation of new technologies as investigational or established.
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> 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.
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> * * *
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> A board-certified M.D. in General Surgery reviewed your appeal, the medical documentation provided and your health care plan benefits for [BCBSM]. It was determined that procedure code 43289 is investigational. Based on the BCBSM Medical Policy titled *Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD),* magnetic esophageal ring insertion for the treatment of GERD is experimental / investigational. The use of this device has not been scientifically shown to improve patient clinical outcomes.

Petitioner's Argument

The Petitioner's authorized representative described the LINX procedure:

> The LINX System is a small flexible band of interlinked titanium beads with magnetic cores. The magnetic attraction between the beads is intended to help the

> LES [lower esophageal sphincter] resist opening to gastric pressures, preventing reflux from the stomach into the esophagus. LINX is designed so that swallowing forces temporarily break the magnetic bond, allowing food and liquid to pass normally into the stomach. Magnetic attraction of the device is designed to close the LES immediately after swallowing, restoring the body's natural barrier to reflux.

In a letter to DIFS dated April 16, 2014, the Petitioner's authorized representative wrote:

> Our understanding of the denial...is that anti-reflux surgery using LINX is "experimental" or "investigational" or "unproven." It is our understanding that [the Petitioner's physician] has furnished the plan with a comprehensive history and physical, medical records and relevant supporting literature which supports approving this procedure. We, of course, are also providing copies of available clinical information supporting [the Petitioner's] desire to have his GERD symptoms resolved using this procedure and demonstrates:
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> 1. That medical necessity for surgical treatment of [the Petitioner's] GERD is beyond dispute in that there is a confirmed diagnosis and continues to suffer symptoms despite a regimen of PPIs; and
> 2. [The Petitioner's physician] has established that using the LINX system with this patient is likely to achieve *an equal or superior outcome* in her clinical situation and is therefore the preferred alternative to another surgical approach....
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> There are no contraindications for [the Petitioner] in that [he] has no allergies to titanium, stainless steel, nickel, or ferrous materials. Moreover, [the Petitioner] is aware of the limitations relevant to MRI, electrical implants (pacemakers, implantable defibrillator, etc.) or metallic implants in the abdomen and has consented to use of LINX. Among the many [reasons] why [the Petitioner] seeks approval for LINX are its significant benefits compared to other surgical procedures:
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> 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.
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> 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.
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> 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.

The Petitioner's physician also wrote in his January 2, 2014 request for prior authorization:

> My patient has been diagnosed with GERD confirmed by pathologic levels of acid exposure defined by pH testing. Patient has failed pharmacologic treatment despite continuous use of reflux medications Patient's reflux symptoms support progression of disease as indicted in their clinical chart which has been included with this request. My patient has an ineffective esophageal sphincter barrier and remains exposed to risks of disease progression including Barrett's esophagitis and adenocarcinoma if their esophageal defect is not surgically corrected. Patient's risk of developing esophageal adenocarcinoma is 90/125 times higher if Barrett's esophagus develops.
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> * * *
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> Based on the clinical data and diagnostic testing done as part of our patient work-up (enclosed) I anticipate the most appropriate surgical approach is likely to be use of a mechanical deivce placed around the incompetent esophageal sphincter to protect the esophagus for harmful gastric reflux. If the intra-operative examination supports the approach, I intend to use LINX.
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> I believe that my patient is likely to be an appropriate candidate. Additional considerations for mechanical sphincter augmentation in this case including
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> - Patient presents with no significant hernia. Therefore it is far more beneficial for this patient to avoid medically unnecessary dissection of their hiatal anatomy, which is required to form a full wrap fundoplication. A surgically created hiatal hernia will put the patient at higher risk for morbidities and future risk of re-herniation. If at surgical presentation a clinically significant hernia is present, a fundoplication technique will be applied.
> - Patient has expressed concerns regarding the loss of ability to vomit and belch following fundoplication. Sphincter augmentation with the mechanical device should allow my patient to maintain the ability to belch and vomit, which is important to their quality of life.
> - Patient has a history of nausea and I am concerned that vomiting, or the attempt to vomit, may lead to herniation of the fundus wrap. In my medical discretion I should avoid a full fundoplication for this patient if possible.
> - Patient has presented with normal sphincter manomoetry, suggesting sphincter failure is dynamic due to gastric distension. Performing a fundoplication on this patient may result in an overcorrection of the sphincter which is associated with significant side effects such as gas bloat syndrome.

> Sphincter correction with a mechanical device is likely to result in reduced risk of this side effect.
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> Given this patient's condition, they require surgical correction of their esophageal sphincter with laparoscopic anti-reflux surgery

The Petitioner's authorized representative also provided several published medical literature articles and other insurers medical policies to support the conclusion that the LINX procedure is not investigational or experimental.

Director's Review

The *Community Blue* certificate, on page 6.3, provides:

> We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment....

The question of whether the LINX procedure is experimental or investigational for treatment of the Petitioner's condition was presented to an IRO as required by section 11(6) of the PRIRA, MCL 550.1911(6). The IRO reviewer is a physician in active practice who is board certified in surgery with a subspecialty in surgical critical care. The IRO reviewer's report included the following analysis and recommendation:

> It is the determination of this reviewer that the LINX Anti-Reflux surgery is not considered experimental/investigational for the treatment of the enrollee's condition.
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> * * *
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> The device has received Federal Drug Administration (FDA) approval for its intended usage of treating Gastroesophageal Reflux Disease (GERD) symptoms. Guidelines published by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), state "the LINX device should be an option available to patients and providers for the management of medically refractory GERD," based on the available evidence, this is considered a viable option for the treatment of GERD.
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> In regard to refractory GERD symptoms in light of maximum medical management, surgical procedures are typically considered in patients with symptoms despite optimal proton pump inhibitor (PPI) therapy and in patients with severe GERD. Surgery is used, however, in less than 1% of eligible GERD patients, and its usage has been decreasing over the last decade. Laparoscopic Nissen fundoplication is the most commonly performed anti reflux operation.
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> While available research has demonstrated a reduction in GERD symptoms using LINX, there is no literature that directly compares this procedure with other procedures such as endoluminal therapy or fundoplication procedures. Despite

> this lack of head to head comparison, postoperative evaluation demonstrates sufficient efficacy consistent with other surgical procedures and a similar safety profile.
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> In conclusion, the LINX Anti-Reflux surgery is not considered experimental/ investigational for the treatment of the enrollee's condition.
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> * * *
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> It is the recommendation of this reviewer that the denial by Blue Cross and Blue Cross of Michigan for the LINX Anti-Reflux surgery be overturned.

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. See MCL 550.1911(15).

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

V. ORDER

The Director reverses BCBSM's adverse determination of March 27, 2014. BCBSM shall provide coverage for 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.

Annette E. Flood
Director

For the Director:

Joseph A. Garcia
Special Deputy Director