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. 140779-001**

Blue Cross Blue Shield of Michigan,
Respondent.

Issued and entered
this 21st day of May 2014
by Randall S. Gregg
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 through the Michigan Education Special Services Association (MESSA). The plan is underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Petitioner's benefits are defined in the *MESSA Super Care 1 2003 Revision Plan Coverage Booklet*. 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 6, 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 a history of gastroesophageal reflux disease (GERD). Her condition has been unsuccessfully treated with a number of proton pump inhibitors. Her physician

requested coverage for a surgical procedure, the LINX Reflux Management System (LINX), to treat her condition. BCBSM denied coverage for the procedure.

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 issued April 4, 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.
>
> 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.
>
> 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.
>
> 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 / investigation. The use of this device has not been scientifically shown to improve patient clinical outcomes.

Petitioner's Argument

In an April 16, 2014 letter submitted for this review, 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 the April 16, 2014 letter, the Petitioner's authorized representative also 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 her GERD symptoms resolved using this procedure and demonstrates:
>
> 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....
>
> There are no contraindications for your member in that [she] has no allergies to titanium, stainless steel, nickel, or ferrous materials. Moreover, your member 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:
>
> > 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.

In a letter dated December 5, 2013, the Petitioner's physician wrote:

> I saw [Petitioner] in my office on November 26th, 2013. It was determined at the office visit that she would be an excellent candidate for the LINX procedure which could relieve her of her life long GERD problems....Her diagnosis to support this procedure is: Laryngopharygeal reflux disease and Gastroesophageal Reflux Disease.

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

Director's Review

The *Super Care 1* coverage booklet, on page 25 includes the following exclusion:

> [S]ervices and supplies that are not medically necessary according to the accepted standards of medical practice, including any services which are experimental or investigational in nature.
>
> Note: Because of ongoing medical research and technological advances, procedures that have been considered experimental may become generally accepted standard treatments. To be covered under this plan, these procedures must be recognized as the standard of care and be medically necessary for the illness or injury being treated.

"Experimental or investigational treatment" is defined in the coverage booklet on page 41 as:

> A service, procedure, treatment, device, drug, or supply that has not been scientifically demonstrated to be as safe and effective for treatment of the patient's condition.

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 physician reviewer is board certified in surgery and has been in practice for more than 15 years. The IRO report included the following analysis and recommendation:

> The MAXIMUS physician consultant determined that the LINX anti-reflux management system is not investigational for treatment of the member's condition.
>
> * * *
>
> The member has signs and symptoms of gastroesophageal reflux disease documented by Bravo pH testing with a DeMeester score of 25. The member has undergone manometry, which demonstrated peristaltic contractions and low amplitude waves. The member's symptoms have not been adequately controlled with proton pump inhibitor therapy.
>
> This member has documented gastroesophageal reflux disease and has failed conservative therapy....[T]here have been a number of reports that demonstrate the safety and efficacy of the LINX system. [Reference omitted.] The Food and Drug Administration has approved [the] LINX device....[An] FDA approval requires both safety and efficacy be demonstrated prior to issuance of such a determination....[A] consensus panel sponsored by the Society of American Gastrointestinal and Endoscopic Surgeons established the safety and efficacy of this procedure as well....[T]his procedure is medically necessary for treatment of the member's condition.
>
> Pursuant to the information set forth above and available documentation...LINX anti-reflux management system is not investigational 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 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. Therefore, the Director finds that the LINX procedure is not investigational for the Petitioner's condition.

V. ORDER

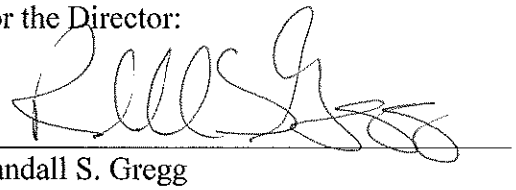
The Director reverses BCBSM's adverse determination of April 4, 2014. BCBSM shall provide coverage for the Petitioner's LINX procedure within 60 days of the date of this order, and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

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:



Randall S. Gregg
Special Deputy Director