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. 138829-001**

Blue Cross Blue Shield of Michigan,
Respondent.

Issued and entered
this 10th day of February 2014
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On January 9, 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 January 16, 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 Choices / Choices II Group Insurance for School Employees* 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 January 27, 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 January 30, 2014.

II. FACTUAL BACKGROUND

The Petitioner has gastroesophageal reflux disease (GERD). His physician requested coverage for a surgical procedure, the LINX Reflux Management System, 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 December 18, 2013. 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

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 January 7, 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:
>
> 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 [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:
>
> 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.

The Petitioner's authorized representative also provided several published medical literature articles, approvals from other insurers for the procedure and also numerous independent medical reviewer opinions to support the conclusion that the LINX procedure is not investigational or experimental. Therefore, the authorized representative argues BCBSM should provide coverage as the procedure is medically necessary.

BCBSM's Argument

In its final adverse determination, BCBSM told the Petitioner:

> 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.

Director's Review

The coverage booklet contains this provision on page 53:

> The following exclusions and limitations apply to the MESSA Choices / Choices II program...
>
> * * *
>
> - Experimental treatment (including experimental drugs or devices) or services related to experimental treatment except as approved by the BCBSM or MESSA medical director. In addition, we do not pay for administrative costs related to experimental treatment or for research management.
>
> * * *
>
> - Services 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.

"Experimental or investigational treatment" is defined in the booklet (page 66) as:

> Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's condition as conventional treatment. Sometimes it is referred to as "experimental services."

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 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 anti-reflux management system is not investigational for treatment of the member's condition.

Rationale:

* * *

The results of the consultants review indicate that this case involves a 20 year-old male who has a long-standing history of gastroesophageal reflux disease since childhood. At issue in this appeal is whether the LINX anti-reflux management system is investigational for treatment of the member's condition.

The member's gastroesophageal reflux disease has required chronic proton pump inhibitor use. Imaging studies have shown a gaping lower esophageal sphincter. A decision was made not to proceed with Nissen fundoplication due to the alteration of normal gastric anatomy and function that results from this procedure. The LINX procedure was recommended to eliminate the need for chronic proton pump inhibitor therapy, which has been suboptimal in efficacy as well as to treat the lower esophageal sphincter gap without altering normal gastric morphology and function.

This member has documented gastroesophageal reflux disease and has had limited results with lifestyle modifications and medical and pharmacologic interventions. Long-term treatment with proton pump inhibitors carries its own inherent risks according to the Food and Drug Administration....[T]here have been a number of reports that demonstrates the safety and efficacy of the LINX system....The Food and Drug Administration has provided an approval letter for the LINX device....[A] FDA approval letter is only provided following the submission of controlled clinical trials that the FDA deems sufficient for demonstration of safety and efficacy....[F]rom a surgical perspective, the LINX does not alter the gastric morphology or function, as other surgical options, such as a Nissen fundoplication....[S]urgical treatment of the member's gastroesophageal reflux disease is medically necessary at this time.

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

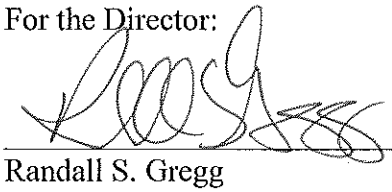
The Director reverses BCBSM's adverse determination of December 18, 2013. BCBSM shall provide coverage for the Petitioner's LINX procedure within 60 days of the date of this order, and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

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