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. 140049-001**

Priority Health,

Respondent.

Issued and entered
this 8th day of April 2014
by Joseph A. Garcia
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 11, 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.*

The Petitioner receives group health care benefits from Priority Health, a health maintenance organization. The Director immediately notified Priority Health of the external review request and asked for the information it used to make its final adverse determination. Priority Health provided its initial response on March 12, 2014. After a preliminary review of the material submitted, the Director accepted the request on March 18, 2014. Priority Health submitted additional information on March 20, 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 March 27, 2014.

II. FACTUAL BACKGROUND

The Petitioner's health benefits are defined in the Priority Health *POS Certificate of Coverage* (the certificate).

The Petitioner has gastroesophageal reflux disease (GERD) and says that proton pump inhibitors such as Prilosec no longer work to control her symptoms. Her physician asked Priority

Health to cover a surgical procedure known as the LINX anti-reflex system to treat her condition. Priority Health denied authorization for the procedure, saying it was investigational and therefore not a benefit.

The Petitioner appealed the denial through Priority Health's internal grievance process. At the conclusion of that process, Priority Health affirmed its decision in a final adverse determination dated February 28, 2014. The Petitioner now seeks a review of that adverse determination from the Director.

III. Issue

Did Priority Health correctly deny coverage for the LINX procedure?

IV. Analysis

Petitioner's Argument

The Petitioner's authorized representative described the LINX procedure in a letter dated March 10, 2014:

> 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.

The Petitioner's authorized representative further 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 [the Petitioner] in that [she] has no allergies to titanium, stainless steel, nickel, or ferrous materials. Moreover, [she] 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 [she] 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 provided medical records and published medical literature to support the contention that the LINX procedure is not investigational or experimental. The authorized representative argues that Priority Health should cover the procedure as medically necessary.

Priority Health's Argument

In its final adverse determination, Priority Health explained its decision to deny coverage for the LINX procedure:

Decision:

Uphold denial - requested coverage will not be provided in accordance with Priority Health Medical Policy 91483-R5 Endoscopic Treatment of GERD and Barrett's Esophagus. Specifically, the LINX Magnetic Sphincter Augmentation procedure is considered experimental and investigational due to limited published evidence proving its safety, efficacy, and durability as compared to standard treatment options.

Facts:

The LINX Magnetic Sphincter Augmentation procedure is considered experimental and investigational and is not a covered benefit in accordance with Priority Health Medical Policy 91483-R5 Endoscopic Treatment of GERD and Barrett's Esophagus which states:

I. POLICY/CRITERIA

B. Priority Health does not provide coverage for other endoscopic treatments* for GERD for the following reasons:

1. The evidence does not permit conclusions on whether endoscopic suturing, radiofrequency energy delivery, or implantation of inert polymers for treatment of gastroesophageal reflux disease improves health outcomes or is as beneficial as established alternatives. Case series data are inadequate to demonstrate improvement in health outcome. The procedures have not been compared to Nissen fundoplication in controlled trials, and the risks and benefits of the procedures compared to Nissen fundoplication are not established.

2. There is no long-term outcome data to show the durability of these procedures.

** This procedure is considered experimental using the Certificate of Coverage definition found in the exclusions section.*

In addition, Medical Policy 91117-R7 Experimental/Investigational / Unproven Care / Benefit Exceptions states:

I. POLICY/CRITERIA

A. Any drug, device, treatment or procedure that is experimental, investigational or unproven is not a covered benefit. A drug, device, treatment or procedure is experimental, investigational or unproven if any of the following apply:

5. Reliable Evidence shows that the prevailing opinion among experts regarding the drug, device, treatment, or procedure is that further studies or clinical trials are necessary to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis.

Definitions:

Reliable Evidence means published reports and articles in the authoritative medical in scientific literature; the written protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device, treatment or procedure.

In addition, Hayes, Inc. brief entitled, "Laparoscopic Magnetic Sphincter Augmentation with the Linx Reflux Management System," dated July 2013, states:

> The Linx system offers a small subset of GERD patients an alternative to traditional surgical treatments for GERD; however, the clinical benefit of this device remains to be proven. Published evidence to date is limited and weak. It is debatable whether or not the U.S. pivotal trial of the device met its primary efficacy outcome, which was defined as ≥ 60% of the patient population achieving normalization or esophageal acid exposure or a ≥ 50% reduction in exposure at 1 year. According to on FDA analysis, the trial did *not* definitively meet this endpoint because the reported 64% success rate came with a confidence interval (CI) of 53.8% to 73%. The lower limit of the CI indicates that the results for this endpoint did not demonstrate that ≥ 60% of patients achieved treatment success.

Director's Review

The certificate (p. 32) excludes coverage for services that are experimental, investigational, or unproven:

> **Non-Covered Services**
>
> Any drug, device, treatment or procedure that is experimental, investigational or unproven. A drug, device, treatment or procedure is experimental, investigational or unproven if one or more of the following applies:
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> a. The drug or device has not been approved by the Food and Drug Administration (FDA) and, therefore, cannot be lawfully marketed in the United States.
>
> b. An institutional review or board or other body oversees the administration of the drug, device, treatment or procedure or approves or reviews research concerning safety, toxicity or efficacy.
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> c. The patient informed consent documents describe the drug, device, treatment or procedure as experimental or investigational or in other terms that indicate the service is being evaluated for its safety, toxicity or efficacy.
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> d. Reliable Evidence shows that the drug, device, treatment or procedure is:
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> i. The subject of on-going Phase I or Phase II clinical trials; or
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> ii. The subject of research, experimental study, or the investigational arm of ongoing Phase III clinical trials; or
>
> iii. Otherwise under study to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis; or

iv. Believed by a majority of experts to require further studies or clinical trials to determine the toxicity, safety, or efficacy of the drug, device, treatment or procedure as compared with a standard means of treatment or diagnosis.

The question of whether the LINX procedure is experimental or investigational for the 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 Magnetic Sphincter Augmentation procedure is not experimental / investigational treatment of the member's condition.

Rationale:

* * *

The results of the consultant's review indicate that this case involves a 47 year-old female who has a history of gastroesophageal reflux disease documented by upper gastrointestinal series, Bravo pH monitoring and EGD. At issue in this appeal is whether the LINX Magnetic Sphincter Augmentation procedure is experimental / investigational treatment of the member's condition.

The member has been treated with proton pump inhibitors without improvement in her symptoms, which have worsened over time. The MAXIMUS physician consultant explained that the surgical option of a Nissen fundoplication alters the normal gastric anatomy and function, whereas the LINX procedure maintains gastric anatomy and function in a normal state. There are significant risks to long term treatment with proton pump inhibitors. The Food and Drug Administration has provided warnings about these risks. The LINX system has been approved by the Food and Drug Administration after review by an expert panel, which requires efficacy and safety data. The physician consultant indicated that professional organizations have also evaluated the data regarding the LINX system and found that it is efficacious. The member has no contraindications to the use of the LINX system. The consultant explained that the requested LINX procedure is medically necessary for treatment of the member's condition and is likely to be effective for her.

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 experimental or investigational for treatment of the Petitioner's condition.

V. ORDER

The Director reverses Priority Health's adverse determination of February 28, 2014. Priority Health shall cover the LINX procedure for the Petitioner 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