

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████

Petitioner,

v

Grand Valley State University, Plan Sponsor,

and

File No. 153133-001

Priority Health Managed Benefits, Plan Administrator,

Respondents.

Issued and entered
this 13th day of May 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On April 7, 2016, ██████████ (Petitioner) filed a request with the Director of Insurance and Financial Services for an external review of that denial under Public Act No.495 of 2006 (Act 495), MCL 550.1951 *et seq.* On April 14, 2016, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan sponsored by the Grand Valley State University (the plan), a self-funded government health plan as defined in Act 495. Priority Health Managed Benefits (Priority) administers the plan. The Director immediately notified Priority of the external review request and asked for the information it used to make the plan's final adverse determination.

Section 2(2) of Act 495, MCL550.1952(2), authorizes the Director to conduct this external review as through the Petitioner were a covered person under the patient's Right to Independent Review Act, MCL550.1901 *et seq.*

The medical issue in this case was evaluated by an independent review organization which provided its analysis and recommendation to the Director on May 2, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in the plan's "Summary Plan Description and

Amendments” (the plan document).

The Petitioner asked the plan to cover the “LINX Reflux Management System.” The LINX procedure, a treatment for gastroesophageal reflux disease (GERD), involves the surgical implantation of a ring of magnetic beads around the esophagus to prevent stomach content from backing up. Priority denied coverage for the procedure, saying it was experimental or investigational for the Petitioner’s condition.

The Petitioner appealed the denial through the plan’s internal grievance process. At the conclusion of that process, Priority issued a final adverse determination dated February 17, 2016. The Petitioner now seeks review of that final adverse determination from the Director.

III. ISSUE

Is the LINX procedure experimental or investigational for the treatment of the Petitioner’s condition?

IV. ANALYSIS

Priority’s Argument

In its final adverse determination, Priority explained its denial:

Decision:

Uphold denial - requested coverage will not be provide in accordance with Priority Health Medical Policy 91483-R7 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.

Petitioner’s Argument

In the information filed with the request for an external review, the Petitioner wrote:

I am suffering from chronic gastroesophageal reflux disease (GERD) as stated by [my physicians]. I have been treated with various types of anti-acid medications, but none of them works on me. I also have attempted treatment with dietary changes without improvements. I suffer the acid burn (the felling of heart burn) due to the acid reflux very seriously EVERY day. I lost about 40 pounds and only eat very limited amount of soft food to avoid more serious burn to my esophagus. My life is horrible and extremely stressful. All doctors indicate surgery is the resolution. I am seeking LINX magnetic sphincter augmentation procedure provided by [my physician] who strongly believes that LINX is my best choice to treat the disease. . . . [The plan] denied my request and then the appeal with statement that the LINX device is experimental and not medically necessary.

Director's Review

The plan document (p. 32) says that covered services must be medically / clinically necessary.¹ The plan document also has this provision (pp. 45, 47):

SECTION 11. GENERAL EXCLUSIONS FROM COVERAGE

The following is a list of exclusions from your coverage. The plan will not cover any service, treatment or supply listed as an exclusion, unless coverage is required under applicable state or federal law.

* * *

Experimental, Investigational or Unproven Services. Any drug, device, treatment or procedure that is experimental, investigational or unproven. . . .

To answer the question of whether the LINX procedure is experimental or investigational and whether it is medically necessary to treat the Petitioner's condition, the Director assigned the case to an independent review organization (IRO) for analysis 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 practice for more than 15 years, and is familiar with the medical management of patients with the Petitioner's condition. The reviewer's report included the following recommendation and analysis:

Recommended Decision:

The MAXIMUS physician consultant determined that the LINX procedure is not experimental / investigational / unproven, but is not medically necessary for treatment of the member's condition.

Rationale:

* * *

The MAXIMUS physician consultant explained that there have been a number of reports that demonstrate the safety and efficacy of the LINX system. The American Society of American Gastrointestinal and Endoscopic Surgeons issued a consensus statement in favor of the LINX procedure being efficacious and safe. The Food and Drug Administration (FDA) has approved the LINX device. [References omitted]

However, the physician consultant explained that the information provided for review does not support that this procedure is medically necessary in this member's case. The member has not had any changes in his symptoms with either antacids or proton pump inhibitors or with lifestyle changes. The consultant noted that the member has a normal EDG and esophageal function study. While a pH study was reported to be

¹ "Medically / clinically necessary" is defined in the plan document (p. 80) as "The services or supplies needed to diagnose, care for or treat [a] physical or mental condition."

abnormal, there was no documentation submitted to support this. The consultant indicated that in addition, there was a handwritten note on the esophageal function study that it was normal study and the author was not convinced that the symptoms were due to reflux and expressed hesitancy in performing LINX.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that LINX procedure is not experimental / investigational/unproven, but is not medically necessary 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. MCL 550.1911(15). The Director, discerning no reason why the IRO's recommendation should be rejected, finds that while the LINX procedure is not experimental or investigation, it is not medically to treat the Petitioner's condition.

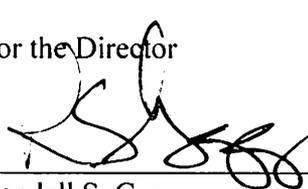
V. ORDER

The plan's denial in its final adverse determination of February 17, 2016, is upheld.

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 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