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. 149840-001**

All Savers Insurance Company
Respondent

Issued and entered
this 16th day of October 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On September 15, 2015 [redacted] Healthcare Advocacy, Inc., 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, MCL 550.1951 *et seq.* The Director accepted the request on September 22, 2015.

The Petitioner receives health care benefits through All Savers Insurance Company. The benefits are administered by United Healthcare Life Insurance Company, (United). The Director notified United of the external review request and asked for the information it used to make its final adverse determination. The Director received United's response on September 28, 2015.

The medical issues in this appeal were analyzed by an independent review organization as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The review organization provided its recommendation to the Director on October 6, 2015.

II. FACTUAL BACKGROUND

The Petitioner has gastroesophageal reflux disease (GERD). Based on her physician's recommendation she requested insurance coverage for the surgical placement of the LINX antireflux system. The LINX procedure involves surgically placing a ring around the lower end of the esophagus. The ring consists of magnetic titanium beads held together by titanium wires. The device prevents stomach content from backing up into the esophagus.

All Savers denied coverage for the LINX. The Petitioner appealed the denial through the plan's internal grievance process. At the conclusion of that process, All Savers affirmed the plan's decision in

a final adverse determination dated September 4, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. Issue

Did All Savers correctly deny coverage for the LINX procedure?

IV. Analysis

All Savers Argument

The Respondent's September 4, 2015 final adverse determination does not provide an explanation of its coverage denial. The final adverse determination does make reference to two provisions in the certificate of coverage: the definition of "experimental or investigational services" and the definition of "unproven services." The Respondent did submit a copy of a medical review it commissioned for this appeal. The review concluded that the LINX device was experimental/investigational and that it was an unproven treatment option.

Petitioner's Argument

The Petitioner's representative argues that LINX is not experimental, investigational, or unproven:

> The LINX System is the first PMA approved surgical device for GERD in the last 20 years, and the data shows an efficacy unprecedented for a GERD device. Studies on the LINX System include two FDA controlled IDE trials with follow-up to 5 years confirming both safety and efficacy. LINX was unanimously endorsed by the selected FDA Advisory Panel and approved by the FDA on March 15, 2012.
>
> ...LINX is an effective treatment for GERD and has a beneficial effect on net health outcomes. This has been established by the FDA through the PMA process. It has been vetted and found safe and effective by the two leading physician societies whose specialty includes anti-reflux surgery have evaluated this procedure and determined it is safe, effective and should be available to use in properly selected patients.
>
> The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), which convened a Technology and Value Assessment Committee (TAVAC), an expert panel charged by the society to assess the safety and effectiveness of LINX. Their report was released in April 2013 and concluded:
>
> > **"On the basis of the available evidence, the LINX device should be an option available to patients for the management of medically refractory GERD."**
>
> After analyzing the data existing at that point in time, data which has been substantially updated and amplified at present, the TAVAC panel made several safety-related observations:

- Safety analyses suggest the LINX procedure was associated with few serious adverse events and no reported mortality
- Long-term (4 to 5-year) follow-up of patients in the feasibility trial have shown no migration or erosion of the device into the esophagus
- Overall, the safety data from the pivotal trial supports a reasonable assurance that the LINX device is safe

With regard to efficacy the panel concluded **"Currently available data demonstrates a reasonable assurance as to the efficacy of the LINX Reflux Management System"** finding:

- Implantation requires minimal dissection and relatively few technical steps when compared to Nissen fundoplication
- The mechanism of action results in a low incidence of difficulty belching
- LINX may provide an option currently lacking in clinical practice for patients with medically refractory GERD who have not yet progressed to end-stage reflux disease with associated complications.

In May 2014 the American Society of General Surgeons (ASGS) Board of Trustees issued the society's Position Statement entitled "LTNX Statement of Support from ASGS."...The ASGS concluded:

> It is the opinion of the American Society of General Surgeons that all that can be done for complete control of the symptoms and complications of GERD has yet to be achieved. Total management will likely rely upon a combination of medical and surgical care in the current and near future. With this idea in mind a durable reproducible surgical procedure that will provide safe control of GERD with minimal side effects is obviously preferred. Based on currently available information and the experience of our members with the procedure we do support the LINX procedure as mechanism for controlling GERD when it is placed by properly trained laparoscopic surgeons with experience in foregut surgery and the management of GERD patients.

The ASGS carefully noted the substantial long-term peer-reviewed literature which supported its Position Statement:

> The first LINX device was implanted in 2007 and FDA approval occurred five years later. Multiple peer review articles have been subsequently published as data and patient experience has accrued. Durable control of symptoms as measure by the GERD-HRQL has been demonstrated beyond 4 years. 85% cessation of PPI use at 6 years has been shown. Greater than 90% of patients are satisfied with their symptom improvement and side effects typically associated with laparoscopic Nissen fundoplication like gas bloat, inability to burp/vomit and persistent dysphagia have been largely eliminated.

Director's Review

The Petitioner's certificate of coverage (page 21) excludes coverage for experimental, investigational or unproven treatment. Experimental/investigational and unproven services are defined on pages 49 and 54 of the certificate:

> **Experimental or Investigational Service(s)** – medical, surgical, diagnostic, psychiatric, substance abuse or other health care services, technologies, supplies, treatments, procedures, drug therapies, medications or devices that, at the time will make a determination regarding coverage in a particular case, are determined to be any of the following:
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> 1. not approved by the U.S. Food and Drug Administration (FDA) to be lawfully marketed for the proposed use and not identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use;
> 2. subject to review and approval by any institutional review board for the proposed use. (Devices which are FDA approved under the Humanitarian Use Device exemption are not considered to be Experimental or Investigational); or
> 3. the subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trial set forth in the FDA regulations, regardless of whether the trial is actually subject to FDA oversight.
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> **Unproven Service(s)** – services, including medications, that are determined not to be effective for treatment of the medical condition and/or not to have a beneficial effect on health outcomes due to insufficient and inadequate clinical evidence from well-conducted randomized controlled trials or cohort studies in the prevailing published peer-reviewed medical literature....

The question of whether the LINX procedure is experimental, investigational, or unproven for the treatment of the Petitioner's condition was presented to an independent review organization (IRO) for analysis. The IRO's reviewer is a physician who has been in practice for more than 15 years and is board certified in surgery. The reviewer is familiar with the medical management of patients with the member's condition. The IRO report included the following analysis and recommendation:

> [T]here have been a number of reports that demonstrate the safety and efficacy of the LINX system. One study reported the results of this laparoscopcially placed device with demonstrated effectiveness at 1 and 2 year follow-up with no evidence of undue side effects....An earlier article also supported the feasibility of this device....The Society of American Gastrointestinal and Endoscopic Surgeons issued a consensus statement in favor of the LINX procedure being efficacious and safe....[F]urthermore, recent studies have provided longer term data on the safety and efficacy of the LINX procedure....The Food and Drug Administration (FDA) has approved for LINX device....[An] FDA approval requires both safety and efficacy be demonstrated prior to issuance of such a

> determination....[T]he post approval data that the FDA has requested is for monitoring and not to demonstrate safety and efficacy....
>
> Pursuant to the information set forth above and available documentation...[the] LINX procedure is not experimental/investigational for treatment of the member's condition.
>
> [Citations omitted.]

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 in this case, finds that the LINX procedure is not experimental, investigational, or unproven for the Petitioner's condition.

V. ORDER

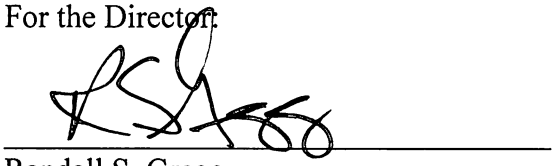
The Director reverses All Saver's final adverse determination of September 4, 2015. All Savers Insurance Company shall immediately provide coverage for the Petitioner's LINX procedure. See MCL 550.1911(17). All Savers Insurance Company shall, within seven days of providing coverage, furnish the Director 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.

Patrick M. McPharlin
Director

For the Director:



Randall S. Gregg
Special Deputy Director