

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

In the matter of:

██████████  
Petitioner

v

File No. 154548-001

Health Alliance Plan of Michigan  
Respondent

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Issued and entered  
this 11<sup>th</sup> day of August 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On July 13, 2016, ██████████, authorized representative of ██████████ (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 550.1901 *et seq.* The Director reviewed the request and accepted it on July 20, 2016.

The Petitioner receives group health care benefits through Health Alliance Plan of Michigan (HAP), a health maintenance organization. The benefits are described in HAP's *HMO Group Subscriber Contract*. The Director notified HAP of the external review request and asked for the information used to make its final adverse determination. HAP responded on July 21, 2016.

Because this case involves a medical issue, it was assigned to an independent review organization, which submitted its analysis and recommendation on August 3, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner has gastroesophageal reflux disease (GERD) and continues to have symptoms despite a regimen of proton pump inhibitors. To treat this condition, his doctor recommended the surgical implantation of a device called LINX for the purpose of preventing stomach acid from entering the esophagus.

HAP denied the Petitioner's request to provide coverage for the procedure. The Petitioner appealed the denial through HAP's internal grievance process. At the conclusion of that process, HAP affirmed its decision in a final adverse determination dated June 15, 2016. The Petitioner now seeks the Director's review of that final adverse determination.

### III. ISSUE

Did HAP correctly deny coverage for Petitioner's proposed LINX surgery?

### IV. ANALYSIS

#### Respondent's Argument

In its final adverse determination, HAP stated:

The Appeal and Grievance Committee carefully reviewed the information regarding the appeal, and upheld the denial. The HAP Benefit Administration Manual (BAM) policy titled Endoscopic Anti-Reflux Procedures (for the treatment of gastroesophageal reflux disease or GERD) excludes coverage for the requested surgery to implant a LINX Reflux Management System, for gastroesophageal reflux disease. This is due to the lack of evidence in the peer-reviewed, published literature to support the long-term safety and efficacy of the procedure.

#### Petitioner's Argument

The Petitioner's authorized representative included in the external review request a copy of a May 10, 2016 letter to HAP explaining why the LINX procedure should not be considered an experimental or unproven procedure. In that letter, the representative wrote that the LINX procedure is safe and effective because it is reversible, involves minimal dissection, keeps the patient's anatomy intact and avoids the complications prevalent in other procedures. Further, the representative states that LINX "has been vetted and found safe and effective by the two leading physician societies whose specialty includes anti-reflux surgery ... " She identified those organizations as the Society of American Gastrointestinal and Endoscopic Surgeons and the American Society of General Surgeons.

The representative stated that there is a large body of medical research establishing that LINX is safe and effective. Finally, she states that the LINX procedure

Center, often used by other payers to determine whether a medical procedure is experimental or unproven.

### Director's Review

To determine whether the requested procedure is experimental or investigational for treatment of the Petitioner's condition, the Director assigned this case to an independent review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician in active practice for more than 15 years who is board certified in surgery and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and recommendation:

The member has been poorly responsive to multiple proton pump inhibitor medications and remains symptomatic. Endoscopy demonstrated reflux to the upper esophagus without Barrett's esophagitis. The member's DeMeester score was 107. The member's treating physician has chosen the LINX procedure as surgical therapy for his condition.

[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 laparoscopically placed device with demonstrated effectiveness at 1 and 2 year follow-up with no evidence of undue side effects ... The Society of American Gastrointestinal and Endoscopic Surgeons issued a consensus statement in favor of the LINX procedure being efficacious and safe, which noted that 85% of patients treated with this procedure are off proton pump inhibitors at 6 years and 90% of these patients had symptom relief without the side effects of fundoplication ... [F]urthermore, recent studies have provided longer term data on the safety and efficacy of the LINX procedure ... [Five] year outcome results demonstrated a 0% unanticipated adverse event rate and significant efficacy ... [T]he LINX procedure is medically necessary for surgical treatment of the member's gastroesophageal reflux disease. The consultant explained that the LINX procedure has become an accepted therapy due to its outcomes as reported in the peer reviewed literature, as well as consensus guidelines of professional organizations and therefore, the Health Plan's policy and rationale for denial in this case are not consistent with the standards of care.

Pursuant to the information set forth above and available documentation ... the LINX procedure is not experimental/investigational/unproven for treatment of the member's condition. [References omitted.]

The Director is not required to accept the IRO's recommendation. *Ross v Health Alliance Plan of Michigan*, 480 Mich 153 (2008). However, the IRO's 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. The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that the proposed LINX procedure is not experimental or investigational and is therefore a covered benefit.

#### V. ORDER

The Director reverses HAP's final adverse determination.

HAP shall immediately provide coverage for the Petitioner's LINX procedure. MCL 550.1911(17). HAP shall, within seven days of providing coverage, furnish the Director with proof it 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, at this toll free telephone number (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:



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Randall S. Gregg  
Special Deputy Director