

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. 149869-001

Health Alliance Plan of Michigan,

Respondent.

Issued and entered
this 26th day of October 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

██████████ (Petitioner) was denied coverage for treatment for his obstructive sleep apnea by his health plan. On September 16, 2015, he filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits from Health Alliance Plan of Michigan (HAP), a health maintenance organization. The Director notified HAP of the external review request and asked for the information it used to make its final adverse determination. The Director received HAP's response on September 21, 2015. After a preliminary review of the material submitted, the Director accepted the request on September 23, 2015.

This case involves a medical issue so the Director assigned it to an independent review organization which submitted its recommendation on October 7, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in HAP's *HMO Subscriber Contract* (the contract).

The Petitioner has obstructive sleep apnea. His otolaryngologist recommended treating the condition with a surgically-implanted upper airway stimulation device and asked HAP to

cover it. HAP denied the request on the basis that the proposed treatment is investigational.

The Petitioner appealed the denial through HAP's two-level internal grievance process. At the conclusion of that process, HAP upheld its denial and issued a final adverse determination dated September 3, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did HAP correctly deny coverage for the proposed implantation of an upper airway stimulation device and related services?

IV. ANALYSIS

Petitioner's Argument

On the external review request form the Petitioner said:

Requesting a hypoglossal nerve stimulator for a diagnosis of obstructive sleep apnea where CPAP methods have failed treatment.

The Petitioner's otolaryngologist explained the need for the therapy in an April 17, 2015, letter to HAP:

Please accept this letter as [the Petitioner's] appeal to Health Alliance Plan's decision to deny coverage for upper airway stimulation (UAS) therapy of the hypoglossal nerve (12th cranial nerve). It is my understanding based on your denial dated 4/10/15 that this procedure has been denied because you feel this treatment option cannot be approved based on insufficient evidence.

The clinical data . . . clearly establishes a sustained clinical benefit at 18 months. . . . But even more important than the clinical data is the potential for this valuable treatment option to have a life changing impact of [his] compromised health condition.

[He] has suffered from severe obstructive sleep apnea for many years. He had a sleep study done in 12/2014 which showed an AHI of 20.7 with desaturations mainly into the 90s and as low as the 80s. He has been on CPAP since then and uses it daily. He also scored a 14 on the Epworth Sleepiness Scale (ESS) which indicates excessive daytime sleepiness. . . . It is my medical judgment that [the Petitioner] requires treatment and will significantly benefit from upper airway stimulation therapy. He meets all patient selection criteria - his BMI is 26.52, he has AP collapse as documented by an endoscopic procedure under conscious

sedation, and he has a confirmatory PSG. For [the Petitioner], this is an excellent treatment option.

Respondent's Argument

In its final adverse determination, HAP explained its denial to the Petitioner's otolaryngologist:

. . . The information we have received does not support approval of this appeal.

The appeal request was reviewed using the submitted documentation. The Administrative Review Committee has decided to uphold our previous denial decision because there is insufficient data in the peer-reviewed, published literature to support the safety, efficacy, and long-term outcomes of implantable upper airway stimulation devices. . . .

HAP had the Petitioner's request reviewed twice by MCMC, an external managed care services company. Both MCMC reviewers concluded that hypoglossal nerve stimulation was considered to be investigational.

Director's Review

HAP denied the request for an implantable upper airway stimulation device on the basis that it was investigational. The contract (pp. 19-20) excludes coverage for services that are experimental or investigational. The term "investigative" is defined in the contract (p. 40).

The question of whether the upper airway stimulation device is investigational for the treatment of the Petitioner's condition was presented to an independent review organization (IRO) for a recommendation 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 otolaryngology and critical care and has been in active practice for more than 18 years. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that hypoglossal nerve stimulation is not investigational for treatment of the member's condition.

Rationale:

* * *

The MAXIMUS physician consultant explained that obstructive sleep apnea is an increasingly prevalent clinical problem with significant effects on both personal and public health. Continuous positive airway pressure (CPAP) has

demonstrated excellent efficacy and low morbidity. Long-term adherence rates with this treatment approach 50%. The physician consultant indicated that although traditional upper airway surgical procedures target the anatomic component of obstruction, upper airway stimulation targets the twin goals of improving anatomic and neuromuscular pathology. After decades of trials demonstrating proof of concept of hypoglossal nerve stimulation in animal and human subjects, the results of a large multicenter, prospective trial were recently published. The consultant explained that this trial demonstrated that hypoglossal nerve stimulation led to significant improvements in objective and subjective measurements of the severity of obstructive sleep apnea. The consultant also explained that this novel approach is the first to combine sleep surgery techniques with a titratable medical device for the treatment of obstructive sleep apnea.

The member has an apnea-hypopnea index of 20.7 and an Epworth Sleepiness Scale score of 14. The member's body mass index is 26.52. On sleep endoscopy, there was snoring, obstruction and narrowing with AP collapse from the soft palate to the oropharynx and base of his tongue. The member has used CPAP and an oral appliance, but these modalities have not been effective in relieving his symptoms. The physician consultant explained that the member would benefit with implantation of the . . . device. The consultant indicated that the Health Plan's rationale for denial of these services was not consistent with accepted standards of care.

Pursuant to the information set forth above and available documentation, the physician consultant determined that hypoglossal nerve stimulation is not investigational and is medically necessary 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 IRO 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 the upper airway stimulation device proposed for the Petitioner is not investigational, is medically necessary, and is a covered benefit.

V. ORDER

The Director reverses HAP's September 3, 2015, final adverse determination. HAP shall immediately cover the proposed upper airway stimulation device and shall, within 7 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 the implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free 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 Michigan county where the covered person resides or in the circuit court of Ingham County. A copy of any petition for judicial review should be sent to the Director 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