

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

In the matter of:

██████████

Petitioner,

v

Oakland County Michigan, Plan Sponsor

and

File No. 150887-001-SF

Navitus Health Solutions, Plan Administrator

Respondents.

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

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a prescription drug by his health plan. On November 13, 2015, ██████████, MD, the Petitioner's authorized representative, 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.*

The Petitioner receives prescription drug benefits through a plan sponsored by Oakland County (the plan), a government self-funded health plan subject to Act 495. Navitus Health Solutions (Navitus) administers the plan's pharmacy benefits. The Director immediately notified Navitus of the external review request and asked for the information it used to make its final adverse determination. Navitus's response was received on November 13, 2015. The Director accepted the request on November 20, 2015, after a preliminary review of the information submitted.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The case was assigned to an independent review organization (IRO) for a review of the medical issue raised. The IRO provided its report to the Director on December 7, 2015.

II. FACTUAL BACKGROUND

The Petitioner's prescription drug benefits are defined in a booklet called *Oakland County Pharmacy Benefit* (the benefit booklet).

The Petitioner has Parkinson's disease and a related illness called "neurologic orthostatic hypotension," a condition characterized by a drop in blood pressure that occurs when a person changes position. This hypotension produces syncope, a loss of consciousness resulting from insufficient blood flow to the brain.

To treat the Petitioner's condition, his physician prescribed the drug Northera, a medication to reduce dizziness and lightheadedness in patients who experience a drop in blood pressure. Navitus declined to authorize coverage.

The Petitioner appealed Navitus's denial through the plan's internal grievance process. At the conclusion of that process Navitus, acting for the plan, issued a final adverse determination dated September 9, 2015, affirming the denial. The Petitioner now seeks review of that final adverse determination from the Director.

III. ISSUE

Should the Petitioner be required to try prescription drugs on Navitus's drug formulary before coverage is allowed for Northera?

IV. ANALYSIS

Petitioner's Argument

The Petitioner's position was explained in a September 17, 2015, letter to ██████████ County that was submitted with the external review request:

This letter is in response to the . . . denial by ██████████ for [the Petitioner] to receive Northera (droxidopa), a medication that is on label and medically necessary for the treatment of neurogenic orthostatic hypotension caused by primary autonomic failure, in this case, Parkinson's disease. . . .

[The Petitioner] is a ██████ year old male with a medical history of neurogenic orthostatic hypotension secondary to Parkinson's disease which was diagnosed in 2012. [He] had started having an increase in pre-syncopal episodes. These episodes have the patient experiencing lightheadedness. [He] has been

increasing his fluid intake which has had a lack of effect on his symptoms. These syncopal episodes put [him] at an increased risk of falling with possible injury. I will be treating [him] with Northera (droxidopa) 100mg capsules. The patient's dosage of Northera will be titrated to a symptomatic response under my direction until he reaches the maximum dosage of 600 mg, TID. I have instructed the patients to continue to increase his fluid intake and to elevate the head of his bed 30 degrees. Since starting therapy with Northera, [the Petitioner] has been seen for follow up and has not been experiencing lightheadedness. I will have [him] continue taking Northera. . . .

Navitus's Argument

In its final adverse determination, Navitus explained its denial:

A decision was made to uphold the denial. This request has not been approved because this medication is a non-formulary medication and not covered based on the Pharmacy and Therapeutics (P&T) Committee guidelines for the coverage of non-formulary medications. All formulary alternatives must be tried prior to approval of this medication. Alternatives include fludrocortisone and midodrine.

Director's Review

Northera is not on the plan's drug formulary. However, according to the plan's final adverse determination, it may be approved if alternative drugs that are on the formulary are tried first without success.

To determine the reasonableness of the plan's requirement, the case was assigned to an IRO for analysis and 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 certified by the American Board of Psychiatry & Neurology in neurology with a subspecialty in clinical neurophysiology and is in active practice.

The IRO report framed the question to be answered:

Question for review: Should the Petitioner be required to try the two (2) formulary drugs listed on Navitus' September 9, 2015 adverse determination before being considered for the requested drug, Northera?

The IRO included the following analysis and recommendation:

Clinical Rational for the Decision:

Parkinson's disease (PD) and neurogenic orthostatic hypotension is a relatively common presentation. The symptoms of orthostatic hypotension, including

dizziness and episodic loss of consciousness while standing, can be quite disabling. The risk of falls is very high. Typically, in this situation, the standard of care includes starting treatment with nonpharmacological measures, such as increasing fluid intake, elevating the head of the bed and compression stockings.

Pharmacological measures employ a variety of medications, including fludrocortisone, midodrine, pyridostigmine and more recently, droxidopa (Northera). The use of these medications could be limited by significant side effects, such as supine hypertension, electrolyte abnormalities (hypokalemia), fluid retention and diarrhea. The use of Northera could result in relatively fewer side effects, but in the absence of side effects, no studies found Northera to have a better efficacy over other available pharmacological treatment options.

Northera (droxidopa) was approved by the Food and Drug Administration (FDA) for treatment of neurogenic orthostatic hypotension in PD in February 2014. Several randomized controlled trials have documented the efficacy of Northera in the management of dizziness and orthostatic hypotension symptoms in patients with PD versus placebo. However, there are no studies currently documenting any superior efficacy of Northera versus other frequently used medications for orthostatic hypotension, such as midodrine or fludrocortisone. No contraindications, significant side effects, or failure to respond to treatment with these other medications have been documented for this enrollee in the clinical information submitted for review.

* * *

Northera has been recommended for this enrollee with PD and neurogenic orthostatic hypotension. Northera is, however, non-formulary for the enrollee's insurance plan. Alternatives listed include midodrine and fludrocortisone. There is no documentation in the clinical information submitted for review regarding side effects or failure to respond to any treatment for orthostatic hypotension with medications other than Northera. Therefore, the enrollee should be required to try the two (2) formulary drugs prior to being considered for the requested drug, Northera.

Recommendation:

It is the recommendation of this reviewer that the denial issued by [REDACTED] [REDACTED] LLC. for the requested drug, Northera be upheld.

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 review

is based on extensive experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to the plan's terms of coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that Petitioner should try the formulary drugs before receiving coverage for Northera.

V. ORDER

The Director upholds the plan's final adverse determination dated September 9, 2015.

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 Michigan 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