

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. 149527-001

Blue Care Network of Michigan,

Respondent.

Issued and entered
this 5th day of October 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

██████████ (Petitioner) was denied coverage for a prescription drug by her health plan.

On August 25, 2015, she 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 has prescription drug coverage from Blue Care Network of Michigan (BCN), a health maintenance organization. The Director notified BCN of the external review request and asked for the information it used to make its final adverse determination. BCN provided its response on August 26, 2015. On September 1, 2015, after a preliminary review of the material submitted, the Director accepted the request.

Because the case involves medical issues, it was assigned to an independent medical review organization which provided its analysis and recommendation to the Director on September 21, 2015.

II. FACTUAL BACKGROUND

The Petitioner was diagnosed with shift work sleep disorder. Her physician prescribed the drug Nuvigil to treat her condition and asked BCN to cover it. BCN denied the request.

The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process, BCN issued a final adverse determination dated August 13, 2015, upholding its denial. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCN correctly deny coverage for Nuvigil?

IV. ANALYSIS

Petitioner's Argument

The Petitioner explained her position on a health insurance complaint form:

After being diagnosed with shift work disorder my doctor prescribed me Provigil. It worked but not all day. She then gave me a Rx for Nuvigil and samples. Nuvigil samples worked great. The prescription was denied d/t diagnosis. Med is authorized for treatment of shift work disorder, OSA [*obstructive sleep apnea*] and narcolepsy. BCN only will approve it for OSA and narcolepsy. I have attempted to appeal but still denied. They will however pay for Provigil which is used for the same treatment of same disorders.

Respondent's Argument

In its final adverse determination BCN said:

Our step two grievance panel . . . reviewed your request for approval for the prescription drug, Nuvigil. The medical documentation submitted does not indicate that the member has met the medical criteria to approve the drug, Nuvigil. Therefore, the Panel maintained the denial.

BCN's 2015 "Custom Drug List Prior Approval and Step Therapy Guidelines" has this says this about coverage Nuvigil:

Coverage is provided for the treatment of narcolepsy or obstructive sleep apnea and in situations where the member has experienced treatment failure of or intolerance to Provigil. Coverage is not provided for shift-work sleep disorder.

Director's Review

Nuvigil is on BCN "Custom Drug List" (formulary) and "is indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea

(OSA), narcolepsy, or shift work disorder (SWD).”¹ In its final adverse determination, BCN denied coverage for Nuvigil because the Petitioner did not meet “the medical criteria to approve the drug.” However, no medical criteria were identified. BCN’s 2015 “Custom Drug List Prior Approval and Step Therapy Guidelines” (p. 7) does say of Nuvigil:

Coverage is provided for the treatment of narcolepsy or obstructive sleep apnea and in situations where the member has experienced treatment failure or intolerance to Provigil. Coverage is not provided for shift-work sleep disorder.

The grievance conference summary indicates that BCN’s denial was really based on the fact that BCN covers Nuvigil but not for shift work disorder - its formulary limits coverage of the drug.

Because BCN provides prescription drug coverage, it is subject to section 3406o of the Insurance Code, MCL 500.3406o, which says:

An insurer² that delivers, issues for delivery, or renews in this state an expense-incurred hospital, medical, or surgical policy or certificate that provides coverage for prescription drugs and limits those benefits to drugs included in a formulary shall do all of the following:

* * *

(c) Provide for exceptions from the formulary limitation when a nonformulary alternative is a medically necessary and appropriate alternative. This subdivision does not prevent an insurer from establishing prior authorization requirements or another process for consideration of coverage or higher cost-sharing for nonformulary alternatives. Notice as to whether or not an exception under this subdivision has been granted shall be given by the insurer within 24 hours after receiving all information necessary to determine whether the exception should be granted.

Therefore, BCN must provide a nonformulary alternative, i.e., in this case it must cover Nuvigil for the Petitioner if it is shown to be “a medically necessary and appropriate alternative.”

The question of whether Nuvigil is medically necessary to treat the Petitioner’s condition was presented to an independent review organization (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 board certified in neurology and sleep medicine and has been in active practice for more than ten years. The IRO’s report included the following analysis and conclusion:

¹ http://www.nuvigil.com/PDF/Full_Prescribing_Information.pdf

² Section 3406o applies to health maintenance organizations. See MCL 500.3503.

Recommended Decision:

The MAXIMUS physician consultant determined that Nuvigil is necessary for treatment of the member's condition.

Rationale:

The MAXIMUS independent physician consultant, who is familiar with the medical management of patients with the member's condition, has examined the medical record and the arguments presented by the parties.

* * *

In an undated letter of appeal, the member's neurologist stated that she has shift work disorder and that armodafinil (Nuvigil) is required. In her complaint form, the member stated that Nuvigil helps her to stay awake and that another medication was not as effective. The MAXIMUS physician consultant explained that Nuvigil has several Food and Drug Administration approved indications, including shift work disorder. Shift work disorder is a circadian rhythm sleep-wake disorder. The physician consultant indicated that Nuvigil has been shown to be beneficial for this condition. The consultant also indicated that there is other evidence that Nuvigil does indeed have a longer duration of action than modafinil (Provigil). Nuvigil is generally considered to be expensive. However, it is also generally considered to be safe and well tolerated. The member tried a generic form of Provigil for this condition and did not find it to be beneficial. The member has responded to Nuvigil and has tolerated it well.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Nuvigil is 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'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. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. See MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that Nuvigil is medically necessary in the treatment of Petitioner's condition and therefore must be covered.

V. ORDER

The Director reverses BCN's August 13, 2015, final adverse determination. BCN shall immediately approve coverage³ of the prescription drug Nuvigil for the Petitioner and 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 Sections, 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



Randall S. Gregg
Special Deputy Director

³ See MCL 550.1911(17).