

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. 153491-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 6th day of June 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

██████████ (Petitioner) was denied coverage for a prescription drug by his health care insurer, Blue Cross Blue Shield of Michigan (BCBSM).

On May 2, 2016, ██████████, the Petitioner's authorized representative, 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.* On May 9, 2016, after a preliminary review of the material submitted, the Director accepted the request.

The Petitioner receives prescription drug coverage through a group plan underwritten by BCBSM. The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM responded on May 17, 2016.

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 May 24, 2016.

II. FACTUAL BACKGROUND

The Petitioner's prescription drug benefits are described in BCBSM's *Preferred Rx Program Certificate SG* (the certificate).

The Petitioner has pyoderma gangrenosum, an uncommon disorder that causes large, painful sores to develop on the skin. His physician assistant prescribed the brand name drug Potaba to treat the condition and submitted a prior authorization request to BCBSM. BCBSM denied the request, saying the drug was excluded from coverage under the Petitioner's drug plan.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated February 22, 2016, upholding the denial. The Petitioner now seeks of that final adverse determination from the Director.

III. ISSUE

Did BCBSM properly deny coverage for Potaba?

IV. ANALYSIS

Petitioner's Argument

In a letter filed with the external review request, the Petitioner's authorized representative wrote:

[The Petitioner] has a longstanding history of disabling pyoderma gangrenosum. He has been previously evaluated at the Mayo Clinic Dermatology Department to confirm this diagnosis. He has been treated with oral steroids, high potency topical steroids, and oral antibiotics. His condition was uncontrolled causing large blisters that would lead to deep, painful ulcerations not allowing him to use his hands or comfortably wear clothing. He is a contractor dependent upon his hands. Outbreaks would render him unable to work.

He is not a candidate for a biologic or other immunosuppressive agent as he suffers from COPD [*chronic obstructive pulmonary disease*] and is at high risk for an infection.

Since starting him on Potaba in January of 2009, his condition has been controlled and he has been able to work and be pain free.

This letter is to appeal your decision to deny Potaba for this patient. We are hoping that this information will allow [the Petitioner] to continue his treatment with Potaba and be wound and pain free.

Respondent's Argument

In its final adverse determination, BCBSM told the Petitioner:

... After review, the denial of prior authorization for Potaba is maintained because this requested medication is excluded from coverage under your prescription drug plan. Therefore, prior authorization cannot be approved.

You are covered under the *Preferred Rx Program Certificate SG*. In **Section 3: Prescription Drugs Not Covered**, on page 18 of the certificate, it explains as follows:

- We do not pay for anything other than covered drugs and services

A Clinical Pharmacist, RPh, reviewed your appeal and your health care plan benefits for [BCBSM] and determined the following:

"The requested medication is excluded from coverage under your Custom Select drug plan."

Director's Review

BCBSM denied authorization for the drug Potaba because it is not included in the Petitioner's drug formulary called the "Custom Select Drug List." However, a health plan that limits coverage for drugs to those on a formulary must provide an exception when a nonformulary alternative is "medically necessary and appropriate." Section 3406o of the Insurance Code, MCL 500.3406o, says:

An insurer 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.

The question of whether Potaba is a medically necessary and appropriate alternative for treatment of the Petitioner's condition was presented to an independent review organization (IRO) for analysis 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 dermatology, has been in active clinical practice for more than 10 years, and is familiar with the medical management of patients with the member's condition. The IRO reviewer's report included the following recommendation and analysis:

Recommended Decision:

The MAXIMUS physician consultant determined that Potaba is not medically necessary for treatment of the member's condition.

Clinical Rationale for the Decision:

* * *

The MAXIMUS physician consultant indicated that Potaba, potassium aminobenzoic acid, has been used with some controversy in the treatment of Peyronie's disease, but there are no published reports in its use for pyoderma gangrenosum or neutrophilic dermatosis of the hands. The physician consultant explained that given the lack of published medical usage for these conditions, the use of Potaba would be considered investigational for the treatment of pyoderma gangrenosum or neutrophilic dermatosis of the hands. The consultant also explained that Potaba is not considered to be standard of care for these conditions.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Potaba is not medically necessary for treatment of the member's condition.

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 coverage. MCL 550.1911(15). The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that Potaba is not medically necessary and is therefore not a benefit under the terms of the Petitioner's coverage.

V. ORDER

The Director upholds BCBSM's February 22, 2016, final adverse determination.

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