

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. 148271-001

Blue Care Network of Michigan,

Respondent.

Issued and entered
this 3rd day of August 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

On June 10, 2015, ██████████, authorized representative of his adult daughter ██████████ (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 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 June 15, 2015. On June 17, 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. The IRO provided its analysis and recommendation to the Director on July 23, 2015.

II. FACTUAL BACKGROUND

The Petitioner's prescription drug benefits are defined in a prescription drug rider.¹ The rider limits coverage to drugs on the "Custom Select Drug List" (the formulary).

The Petitioner has chronic cystic acne. Her doctor prescribed the prescription drug Accutane to treat the condition and asked BCN to authorize coverage. BCN denied the request, saying it was excluded from coverage because it is not on BCN's formulary.

¹ The "Custom Select Drug List \$4 / \$15 / \$40 / \$80 / \$20% / 20% Prescription Drug Rider."

The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process, BCN issued a final adverse determination dated May 29, 2015, upholding the denial. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCN properly deny prescription drug coverage for Accutane?

IV. ANALYSIS

Respondent's Argument

BCN covers some drugs for acne treatment but not Accutane (see 2015 "Custom Select Drug List," p. 41). In its final adverse determination, BCN told the Petitioner that it denied coverage because Accutane is not on its formulary:

Our Step Two grievance panel, which consists of our Senior Medical Director and Vice President of Customer Service, reviewed your request for approval for the prescription drug Accutane, and upheld the previous denial. The medication is excluded from your Custom Select Drug List. Therefore it is denied.

Petitioner's Argument

In a June 5, 2015, letter filed with the request for an external review, the Petitioner stated:

I submitted for prescription drug coverage for Accutane (or generic equivalent) for chronic cystic acne. I am a [REDACTED] year old college student and my acne has progressed from mild to very severe. My skin no longer responds to topical or antibiotic therapies. In addition I have developed an allergy to benzoyl peroxide limiting cleansing medications.

In the course of my treatment, dermatologists have tried:

- Clindamycin phosphate; Clindamycin-Benzoyl Perox gel; Mupirocin; Tretinoin; Doxycycline Hyclate; Minocycline and Benzoyl Peroxide with Sulfa.

At this point, and given the severity of my condition and lack of responses to other treatments, it is the opinion of my physicians that Accutane is entirely warranted and the only viable treatment for my severe cystic acne.

* * *

I am requesting a review as I have already enrolled in the iPLEDGE FDA program to allow me to start Accutane (4-14-15) when I learned that BCN would not cover the eight month regimen. Because of the timing involved in the iPLEDGE program and the need for pregnancy testing every 30-days, I am currently forced to pay upwards of \$400 for a 30-day supply because of the denial of drug coverage for Accutane (or generic equivalent) for the course of treatment. . . .

Director's Review

BCN denied coverage for Accutane because it is not on the formulary for the Petitioner's health plan. However, section 3406o of the Michigan Insurance Code requires an exception to the formulary limitation when a nonformulary alternative is a medically necessary and appropriate alternative:

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. MCL 500.3406o.

The question of whether Accutane is a medically necessary and appropriate alternative to treat 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; is an assistant professor at a university-based school of medicine; is published in peer review literature; is familiar with the medical management of patients with the Petitioner's condition; and is in active practice. The IRO reviewer's report included the following analysis and recommendation:

Reviewer's Decision and Principal Reasons for the Decision:

It is the determination of this reviewer that the prescription drug Accutane is medically necessary for the enrollee's condition.

Clinical Rationale for the Decision:

* * *

The treatment of the prescription drug Accutane is rendered according to generally accepted standards of medical practice. Accutane is a standard treatment in patients with moderate to severe cystic acne, who have failed standard first line therapy such as topicals and oral antibiotics. The treatment is clinically appropriate as the enrollee is noted to have severe disease which will cause scarring. The treatment is not primarily noted to be for the convenience of the enrollee or provider. The treatment is used in a manner consistent with its label. Accutane is the only option for this enrollee. The treatment is not regarded as experimental as it is Federal Food and Drug Administration (FDA) approved and supported in the literature.

. . . The enrollee has tried topical clindamycin, Benzacilin, mupirocin, tretinoin, oral doxycycline, oral minocycline and a sulfa medication. The enrollee has had a reaction to benzoyl peroxide. Accutane is a standard treatment in patients with moderate to severe cystic acne, who have failed standard first line therapy such as topicals and oral antibiotics. Accutane is the only option for this enrollee. Accutane is medically appropriate and medically necessary in the treatment of this enrollee.

Recommendation:

It is the recommendation of this reviewer that the denial issued by BCN for the prescription drug Accutane be overturned.

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.

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that Accutane is a medically necessary and appropriate alternative to treat the Petitioner's condition and therefore BCN must make an exception to its formulary limitation.

V. ORDER

The Director reverses BCN's May 29, 2015, final adverse determination. Pursuant to MCL 550.1911(17), BCN shall immediately cover the prescription drug Accutane 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 Section, toll free at (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 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