

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. 152042-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 2nd day of March 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

On February 3, 2016, ██████████ (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 Director accepted the request on February 4, 2016.

The Petitioner receives prescription drug coverage through an individual health plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are defined in BCBSM's *Blue Cross Premier Platinum Benefits Certificate*. The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM provided its response on February 15, 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 February 18, 2016.

II. FACTUAL BACKGROUND

The Petitioner is ██████████ years old and has numerous adverse health conditions: chronic diarrhea, impaired fasting glucose tolerance, chronic insomnia, hypercholesterolemia, depression, obesity, vitamin D deficiency, and gastroesophageal reflux disease (GERD). Her physician prescribed the brand name prescription drug Ambien CR for her insomnia. BCBSM denied coverage for the drug.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated January 19, 2016, affirming its denial. The Petitioner now seeks the Director's review of this adverse determination.

III. ISSUE

Did BCBSM properly deny prescription drug coverage for brand name Ambien CR?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination to the Petitioner, BCBSM stated:

Your plan does not cover name brand name drugs when there is a generic equivalent available.

You are covered under the *Blue Cross Premier Platinum Benefits Certificate*. As indicated on Page 80 of the *Certificate*, brand name drugs are not covered when a generic equivalent is available. A Clinical Pharmacist, RPh, reviewed the information submitted...and determined:

Your Custom Select drug plan does not cover brand name drugs when a generic product is available. The requested brand name drug, Ambien CR, has a generic available, Zolpidem CR, and is therefore excluded from the prescription benefit. Additional covered alternatives include: generic Sonata (Zaleplon), generic Dalmane, generic Prosom, generic Restoril, and Rozerem.

Because the requested prescription drug is excluded from coverage when a generic is available, authorization cannot be approved. If you choose to purchase Ambien CR, you will be responsible for the non-covered charges.

Petitioner's Argument

In a letter dated January 30, 2016 accompanying her request for an external review, the Petitioner provided an extensive history of her medical problems and explained why she felt it was imperative that coverage be provided for a brand name insomnia medication rather than a generic drug. The Petitioner states that she has been taking Ambien CR for several years without any problems. In December 2015, she changed her insurer from US Health and Life Insurance Company to BCBSM. BCBSM refused to continue her coverage for Ambien CR and required her to change to the generic drug zolpidem. She says she does not want to use that drug because she has been told that generic drugs include dyes and fillers that are not in the brand name drug. She is not sure the generic drug will be safe for her.

The Petitioner also submitted a letter dated January 27, 2016 from her physician who wrote:

I am the Internist taking care of [Petitioner]. I am writing as a follow-up to the prior appeal regarding her Ambien CR. To review, the information we had previously given you is that she has had a side effect on Sonata, nightmares on Trazodone. Generic Ambien did not work. She has a history of multiple drug intolerances and the Ambien CR brand works well with no side effects. I had recommended she stay on the current medication as she would have high risk of side effects if she tried other options.

To further clarify, she has had chronic gastrointestinal problems with various foods and drugs for over 5 years. Her symptoms can include severe diarrhea, vomiting, and headaches. By changing the Ambien CR brand name which works well for her without a side effect, she could have an adverse reaction which could seriously jeopardize her health.

Due to her multiple drug sensitivities and gastrointestinal effects from ingested items, a generic option would not be recommended. Certain generics in the past have caused her side effects such as headaches, hallucinations, abdominal pain, diarrhea and cramping. Generics are known to contain various fillers and dyes which could be causing her these medical complications.

As her physician, I am again recommending that it is imperative that no changes be made and that she continue on the brand Ambien CR 12.5 mg as prescribed as she is doing well on this medication.

Director's Review

BCBSM denied authorization for the brand name drug Ambien CR, ruling that brand name drugs such as Ambien CR are not covered when there is a generic equivalent available. However, the Michigan Insurance Code provides for an exception from the formulary limitation when a nonformulary alternative is a medically necessary and appropriate alternative. Section 3406o of the Insurance Code, MCL 500.3406o, states in pertinent part:

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....

The question of whether brand name Ambien CR is a medically necessary and appropriate alternative under section 3406o to treat 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 reviewer is a physician in active practice who is certified by the American Board of Internal Medicine. The reviewer is an assistant professor of medicine at a university based school of medicine. The IRO reviewer's report included the following analysis and conclusion:

It is standard of care to treat patients with generic medications when available. By law, and to get Federal Food and Drug Administration (FDA) approval, generic medications must contain the exact same active ingredient as the original branded medication. The differences in generic and brand medications are usually fillers and dyes used in the manufacturing of the medication, but by law, the generic medication must have the same therapeutic effect and active ingredients as the original branded medication. As such, it is reasonable and standard of care for the enrollee to be treated with zolpidem CR for her condition (insomnia) instead of the branded Ambien CR.

Although the Medication Request Form states the enrollee had taken zolpidem (generic Ambien) from November 2010 through June 2011, it has not been documented in the medical records submitted for review that the enrollee has had intolerances or adverse reactions to the covered generic equivalent medication of Ambien CR (zolpidem CR). Since the enrollee has not tried zolpidem CR for treatment of her insomnia, it cannot be stated that she has failed such therapy.

According to MCL 500.3406o, subsection (c), the insurer providing prescription drug coverage with formulary restrictions must provide exceptions from the formulary limitation when a nonformulary alternative is medically necessary and there is an appropriate alternative. Specifically in this case, since there is a generic medication equivalent for the requested branded medication, and since the enrollee has not been documented to have tried or failed treatment with the generic medication equivalent, this statute would not take effect.

Additionally, the documentation provided does not prove that the request for branded Ambien CR is not primarily for the convenience of the enrollee. The enrollee states that she has been on this medication for years, but also in her own January 30, 2015 letter states that she has been on generic medications for other current medical illnesses. As such, based on the Michigan statute and in consideration of the letters written by the enrollee and treating physician, medical necessity has not been established for the enrollee to be covered for branded Ambien CR.

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 the present case, finds that BCBSM's denial of Ambien CR to treat the Petitioner's condition is consistent with the terms of the certificate and Michigan law.

V. ORDER

The Director upholds BCBSM's January 19, 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

A handwritten signature in black ink, appearing to read 'RS Gregg', written over a horizontal line.

Randall S. Gregg
Special Deputy Director