

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. 145152-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 12th day of January 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On December 2, 2014, ██████████ authorized representative of ██████████ (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.* After a preliminary review of the material submitted, the Director accepted the request on December 9, 2014.

The Petitioner receives prescription drug benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan Mutual Insurance Company (BCBSM). 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 December 18, 2014.

To address the medical issues in the case, the Director assigned this case to an independent medical review organization which provided its analysis and recommendation on December 24, 2014.

II. FACTUAL BACKGROUND

The Petitioner's prescription drug benefits are defined in BCBSM's *Preferred RX*

*Program Certificate SG*¹ (the certificate).

The Petitioner has been taking the brand name prescription drug Lipitor, a medication used to treat high cholesterol, because the generic version of the drug produced side effects. When her doctor prescribed brand name Lipitor, BCBSM refused to cover it.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM affirmed its denial in a final adverse determination dated November 25, 2014. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Is BCBSM required to cover brand name Lipitor for the Petitioner?

IV. ANALYSIS

Petitioner's Argument

The Petitioner wants BCBSM to cover the brand name drug Lipitor so she can continue to use it.² She maintains that the generic version of Lipitor produces side effects. In the request for external review, the Petitioner's doctor wrote:

[The Petitioner] has been in her current non-generic medications for more than 10 years. With the Lipitor – patient presented flatulence, nausea, diarrhea, bysypsis [*sic*] with the generic brand. There are no side effects with the brand name.

BCBSM's Argument

In its final adverse determination, BCBSM explained the reasons for its denial of preauthorization to the Petitioner:

You are covered under the *Preferred RX Program Certificate*. As explained on Page 3.1 of the certificate, brand name drugs with a generic equivalent available (multi-source brand) are not a covered benefit.

In addition a clinical pharmacist reviewed the documentation submitted by [your doctor] and concluded:

¹ BCBSM form no. 910F, federal approval 09/13, state approval 03/14.

² On the request for external review form the Petitioner says BCBSM had previously approved brand name Lipitor for her.

The member's prescription drug plan does not cover brand name drugs when a generic product is available. The requested brand name drug, Lipitor, has a generic available and is therefore excluded from the prescription benefit.

Covered alternatives include: generic Zocor (simvastatin), generic Pravachol (pravastatin), generic Lescol (fluvastatin), and generic Mevacor (lovastatin).

Because your coverage specifically excludes coverage for brand-name prescription drugs when a generic equivalent is available, authorization cannot be approved.

Director's Review

The certificate (p. 3.1), under "Prescription Drugs Not Covered," says:

We will not pay for the following:

- Brand-name drugs with a generic equivalent available (multi-source brand).

BCBSM declined to cover brand name Lipitor because its formulary includes generic alternatives. However, Michigan law requires health insurers that provide prescription drug coverage to make an exception to a formulary limitation 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:

(a) Provide for participation of participating physicians, dentists, and pharmacists in the development of the formulary.

(b) Disclose to health care providers and upon request to insureds the nature of the formulary restrictions.

(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 brand-name Lipitor is a medically necessary and appropriate alternative for the Petitioner 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 certified by the American Board of Neurological Surgery; an associate professor of surgery at a university-based school of medicine; published in the peer reviewed literature; and in active practice. The IRO reviewer's report included the following analysis and recommendation:

According to the limited documentation submitted for review, the enrollee has hypercholesterolemia. The standard of care for treatment would be the utilization of either the brand name medication Lipitor or the generic variant (atorvastatin).

The enrollee's request to substitute the brand name medication Lipitor for use as opposed to the generic variant has been denied by [BCBSM] given that the enrollee's Custom Select drug plan does not cover brand name drugs when a generic product is available. The requested brand name medication, Lipitor, has a generic available, Atorvastatin, and is therefore excluded from the prescription benefit.

A study at the 2010 Congress of the European Society of Cardiology allegedly showed that the originator drug Lipitor was more beneficial than any of its generic statin equivalents. But, in fact the study merely showed that the different potencies of statins were not taken adequately into consideration during the generic switch. The conclusions underscore that statin generics do have essentially the same safety and efficacy as brand name Lipitor and may have implications for new atorvastatin generics that have recently entered the market.

There is no literature to support the presence of increased symptoms including flatulence, nausea, diarrhea, and dyspepsia when utilizing variants of Lipitor. Therefore, the brand name medication Lipitor is not medically necessary over the generic variant.

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 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, finds that brand-name Lipitor is not medically necessary to treat the Petitioner's condition and BCBSM does not have to cover it.

V. ORDER

The Director upholds BCBSM's final adverse determination of November 25, 2014.

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.

Annette E. Flood
Director

For the Director:



Randall S. Gregg
Special Deputy Director