

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. 151595-001

Blue Cross Blue Shield of Michigan,
Respondent.

Issued and entered
this 3rd day of February 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for the brand name prescription drug Lescol XL by his health insurer, Blue Cross Blue Shield of Michigan (BCBSM).

On January 6, 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.* After a preliminary review of the material submitted, the Director accepted the request on January 13, 2016.

The Petitioner receives group prescription drug benefits through a 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 provided its response on January 19, 2016.

To address the medical issue in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on January 25, 2016.

II. FACTUAL BACKGROUND

The benefits are defined in BCBSM's *Preferred Rx Program Certificate SG*¹ (the certificate).

The Petitioner has end-stage renal disease from focal segmental glomerulosclerosis. He received a kidney transplant in 2009. He also has diabetes, hypertension, and hyperlipidemia. When his

¹ BCBSM form no. 910F.

physician prescribed and requested coverage for the brand name drug Lescol XL to help control his cholesterol, BCBSM denied coverage, saying there was a generic version of the drug available.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its decision in a final adverse determination dated December 14, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for the brand name prescription drug Lescol XL to treat the Petitioner?

IV. ANALYSIS

Petitioner's Argument

In the request for external review, the Petitioner's authorized representative wrote:

Patient needs brand name Lescol medication. He can't tolerate the generic brand, Fluvastatin Sodium. While taking generic brand, he had diarrhea and loss of appetite. Once he discontinued generic brand medication, his symptoms resolved. Also patient's cholesterol is maintained on Lescol.

BCBSM's Argument

In its final adverse determination, BCBSM's representative told the Petitioner:

. . . [Y]our plan does not cover brand-name drugs with a generic equivalent available. Because Lescol XL is a brand-name drug that has generic equivalents available, it is not covered under your plan.

To ensure all possible consideration was given, a Clinical Pharmacist, RPh reviewed the submitted appeal, along with the notes from your Conference, and determined the following:

Your Custom Select drug plan does not cover brand name drugs when a generic product is available. The requested brand name drug, Lescol XL, has a generic available and is therefore excluded from the prescription benefit. Covered alternatives may include generic Lipitor, generic Mevacor.

Therefore, preauthorization for Lescol XL could not be approved. If you have the prescription filled, you will be liable for the charges, as well as for any past purchases of this medication.

Director's Review

The certificate (p. 17) says:

Section 3: Prescription Drugs Not Covered

We will not pay for the following:

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

The Petitioner's drug plan limits its coverage to drugs on a formulary; that limitation excludes any brand name drug that has a generic equivalent on the formulary. However, state law allows an exception if a nonformulary alternative, e.g., Lescol XL in this case, is 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 the brand name drug Lescol XL is a medically necessary and appropriate formulary alternative to treat 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 Internal Medicine with a subspecialty in nephrology; is published in the peer reviewed medical literature; is familiar with the medical management of patients with the Petitioner's condition; and is in active practice. The IRO report included the following analysis and recommendation:

Clinical Rationale for the Decision:

The standard of care for treatment of hyperlipidemia in a patient such as this, with an increased risk of cardiovascular disease (diabetes, hypertension, and end-stage renal disease) consists of the use of generic statins.

The enrollee has side effects with generic fluvastatin, which according to the United States Food and Drug Administration (FDA) website, is produced by only one

manufacture. However, the 2016 Physician's Desk Reference and Micromedex indicates other generic statins aside from fluvastatin have FDA approval for hyperlipidemia, including pravastatin, lovastatin, atorvastatin, and simvastatin. There is no mention of contraindications or side effects to any of these agents for this enrollee per the documentation submitted for review, and all of them are more potent at lowering the low-density lipoprotein (LDL) than Lescol XL. For the reasons noted above, brand name prescription drug Lescol XL is not medically necessary for this enrollee.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for brand name prescription drug Lescol XL be upheld.

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 the IRO recommendation should be rejected, accepts the recommendation and finds that Lescol XL is not medically necessary to treat the Petitioner.

V. ORDER

The Director upholds BCBSM's December 14, 2015, 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 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.

Patrick M. McPharlin
Director

For the Director:



Randall S. Gregg
Special Deputy Director