

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. 150960-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 28th day of December 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

On November 19, 2015, ██████████ (Petitioner), filed with the Director of Insurance and Financial Services a request for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The request concerned the denial of coverage for a drug prescribed by the Petitioner's doctor. The Director accepted the request on November 30, 2015.

The Petitioner receives prescription drug coverage through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are described in BCBSM's *Preferred Rx Program Certificate SG*. The Director notified BCBSM of the external review request and asked for the information used to make its final adverse determination. BCBSM provided its response on December 3, 2015.

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 December 14, 2015.

II. FACTUAL BACKGROUND

The Petitioner is █ years old and has a history of hyperlipidemia (high cholesterol). The Petitioner's physician prescribed Crestor 5 mg for treatment of his condition and requested that BCBSM authorize coverage for the drug. BCBSM denied the request. The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated October 30, 2015, affirming the denial. The Petitioner now seeks from the Director a review of the denial.

III. ISSUE

Did BCBSM properly deny prescription drug coverage for Crestor 5 mg?

IV. ANALYSIS

Respondent's Argument

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

You are covered under the *Preferred Rx Program Certificate SG*. Under **Section 2: Prescription Drug Coverage**, under **Mandatory Prior Authorization**, on page 12 of the certificate, it states the following:

- For some drugs, certain clinical criteria must be met before coverage is provided. When prior authorization of a prescription drug is required, authorization must be obtained from Blue Cross Blue Shield of Michigan (BCBSM) before we will consider payment of the drug;
- If the required prior authorization is not requested or approval is not obtained, we will deny payment and you will be responsible for 100 percent of the pharmacy's charge; and
- The prescribing physician requesting prior authorization should demonstrate that the drug meets BCBSM's prior authorization criteria.

A Clinical Pharmacist, RPh, reviewed your claim, your appeal, and your health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM) and determined the following:

The coverage guidelines for your Custom Select Drug List benefit require criteria be met before coverage can be authorized. Our criteria for coverage of this medication require that you try at least two generic statins one of which is generic Lipitor (atorvastatin) and one of which is high dose (greater than or equal to 40 mg). Options for generic statins include atorvastatin, lovastatin, pravastatin, and simvastatin. We have no record that you have tried at least two generic statins; one of which is generic Lipitor (atorvastatin) and one of which is high dose (greater than or equal to 40 mg). Please note: Crestor is also a statin medication.

Petitioner's Argument

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

My family history has prevented my mother of taking statins meds my doctor put me on 5mg of Crestor in May 15 due to prior family history issues with these type drugs to see if my body could stand them. In 6+ months my levels have dropped from the mid 300's to low 200's with this dosage without major body side effects. BC/BS of Michigan refuses to pay for 5mg of Crestor until I have taken a min of 40mg of a generic statin drug. That is 8 times higher dosage than my doctor currently has me on for 6 months for them to save a few dollars versus

my overall health. I'd take a generic 5mg but there is none available with such a low dosage.

Director's Review

The Petitioner has not completed the requirements of BCBSM's medical policy regarding the authorization for treatment with Crestor. The Petitioner has described the medical reasons why he believes he should not be required to follow those requirements. Under some circumstances, an individual may be excused from meeting an insurer's prior authorization requirements. Section 3406o of the Michigan Insurance Code, MCL 500.3406o, provides:

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 questions of whether BCBSM's criteria were medically appropriate 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 certified by the American Board of Family Medicine and is an assistant professor at a university based school of medicine. The IRO reviewer's report included the following analysis and conclusion:

The enrollee is currently being treated for hypercholesterolemia. The standard of care for treatment is reduction of the low density lipoprotein (LDL) level utilizing diet/behavior modification and medication while monitoring for adverse liver and muscle effects.

The health plan coverage criteria guidelines for Crestor requires documentation of failed treatment with at least two generic statins one of which is generic Lipitor (atorvastatin) and one of which is high dose (greater than or equal to 40 mg) with options for generic statins including atorvastatin, lovastatin, pravastatin and simvastatin.

The provided documentation cites the enrollee's family history (his mother experienced rhabdomyolysis with statin treatment) for initiating Crestor in lieu of generic therapy. Current evidence based literature lists the risk factors of rhabdomyolysis as Asian race, age older than seventy (70) years, female sex, impaired liver/renal function, low body mass, untreated hypothyroidism, alcohol abuse and substance abuse and suggests caution when two (2) or more of the factors are present. These risk factors are not described in the provided documentation and do not include family history of rhabdomyolysis.

Additionally, the use of the generic statin pravastatin has been shown to have a

low risk of myopathy. This low risk, which is thought to be derived from its hydrophilic nature which it shares with Crestor, would make pravastatin a medically reasonable initial agent in a high risk individual. As such, the literature does not support the use of Crestor over the use of generic step therapy given the enrollee's family history of rhabdomyolysis.

* * *

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for Crestor 5 mg be upheld. [References omitted.]

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 certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason to reject the IRO's recommendation, finds that BCBSM's denial of prior authorization for the prescription drug Crestor 5 mg was consistent with the terms of the *Preferred Rx Program Certificate* and Michigan law.

V. ORDER

The Director upholds BCBSM's October 30, 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 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