

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████
Petitioner

v
Blue Cross Blue Shield of Michigan
Respondent

File No. 145791-001

Issued and entered
this 11th day of February 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On January 13, 2015, ██████████ (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 January 21, 2015.

The Petitioner receives prescription drug benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The prescription drug benefits are defined in BCBSM's *Preferred RX Program Certificate SG* and its *Custom Select Drug List*. 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 January 28, 2015.

To address the medical issues in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on February 4, 2015.

II. FACTUAL BACKGROUND

The Petitioner has a history of Attention Deficit Disorder with hyperactivity (ADHD) for which he has been taking brand name Adderall XR. In the past, BCBSM had approved coverage for the drug in its brand name form. In December 2014, the Petitioner's physician requested authorization for continued coverage of the brand name drug. BCBSM denied the request.

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 December 25, 2014. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny preauthorization and coverage for the prescription drug Adderall XR?

IV. ANALYSIS

Petitioner's Argument

The Petitioner stated in his request for an external review:

I have tried taking the generic version of Adderall XR twice and each time I've found it to cause severe side effects such as psychotic mood swings. I've been taking the brand version of Adderall XR successfully for many, many years (10+) and have found that to work the best out of all the meds I've tried. In December 2014 BCBSM started to deny the brand coverage and won't cover it since there is a generic version of the drug. My Dr. has provided documentation supporting my claims to no avail. BCBSM isn't understanding that the generic is bad for me.

In a letter to BCBSM dated December 17, 2014, the Petitioner's physician explained the reasons for requesting coverage of brand name Adderall XR:

The patient has history of Attention-deficit Disorder, which was controlled at one time with generic Adderall. Overtime however, the patient became intolerant to the generic and thus required an adjustment to brand name medication. Their symptoms overall have been stable since this adjustment.

Given the patients' history with generic medication, it would be medically necessary to continue him on brand name Adderall XR.

BCBSM's Argument

In its final adverse determination, BCBSM wrote:

Your prescription drug benefits are provided under the *Preferred RX Program Certificate* and your group uses the *Custom Select Drug List*. Because there is a generic version of Adderall available, brand-name Adderall is excluded from coverage under the *Custom Select Drug List*. **Section 3: Prescription Drugs Not**

Covered in the *Certificate* states that anything other than covered drugs and services are not a benefit of the coverage. Thus, brand-name Adderall is not a benefit under your plan.

* * *

Covered stimulant alternatives include: generic methylphenidate products (options include Concerta, Metadate, Methylin, Ritalin). Covered non-stimulant alternatives include: generic Kapvay (clonidine ER), and Strattera. Please refer to your custom select drug list for a complete list of covered alternatives....

Director's Review

BCBSM's *Preferred RX Program Certificate SG* (page 17) provides that BCBSM will not pay for brand-name drugs that have a generic equivalent available. BCBSM denied coverage for Adderall XR because there are covered generic equivalents available to treat the Petitioner's condition. However, Michigan law (MCL 500.3406o) requires health insurers providing prescription drug coverage to make an exception to a formulary limitation when a nonformulary alternative is medically necessary and appropriate:

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 Adderall XR is a medically necessary and appropriate alternative for treatment of the Petitioner's condition was presented to an independent review organization (IRO) 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 clinical practice who is certified by the American Board of Family Medicine and is a senior staff physician at an east coast metropolitan hospital. The reviewer's report included the following analysis and recommendation:

ADHD is a psychiatric disorder of the neurodevelopmental type. Symptoms are varied and are dependent on the age of the individual and the subtypes present in the individual. Usually, there are problems with inattentiveness, hyperactivity or impulsiveness that is not appropriate for the person's age. In adults, ADHD

symptoms may present differently than in children. Symptoms of an inability to relax or the ability to talk excessively in social situations can be present; impulsiveness in relationships and sensation seeking behaviors are often common. Addictive behaviors involving substance abuse or gambling are also common. It is estimated that between 2-5% of adults have ADHD; however, most adults remain untreated. The standard of care for the treatment of ADHD involves a combination of counseling and the use of stimulants and/or non-stimulant medications. Stimulant medications are the treatment of choice; these include dextroamphetamine, dextroamphetamine/amphetamine, methylphenidate, dexmethylphenidate, and lisdexamfetamine; along with their various brand name counterparts including Adderall, Concerta, Ritalin, Focalin, Vyvanse, and Procentra. The exact mechanism of action of the stimulant medications is unknown but it does stimulate central nervous system (CNS) activity by blocking the reuptake of norepinephrine and increasing the release of the norepinephrine and dopamine in to the extra neuronal space. There are a number of non-stimulant medications that may be used as alternatives; these include atomoxetine (Strattera), bupropion (Wellbutrin), guanfacine (Tenex, Intuniv), and clonidine (Catapres, Kapvay). The exact mechanism of action in the treatment of ADHD with these medications is unknown but can involve inhibiting norepinephrine reuptake, to stimulating alpha 2 adrenergic receptors. Studies do not exist that compare the two groups of medications, but they appear to be equal in regards to their side effects. In this case, the enrollee was treated with a stimulant medication of Adderall XR, the generic form being that of dextroamphetamine/amphetamine. Adderall is a mixture of various salts, 75% dextroamphetamine and 25% levoamphetamine. The extended release form is designed to provide a more consistent therapeutic effect than taking two (2) doses of the nonextended release brand or generic forms four (4) hours apart.

The brand name of Adderall XR was not medically necessary for the enrollee's condition as it was not the only medication available for treatment of the enrollee's condition. The enrollee states that he was tried on the generic brand twice and was subsequently switched to the brand name. The documentation submitted for review does not indicate any medication trials that are covered under the Custom Select Drug List that were attempted which may have the same therapeutic affect without the untoward side effects. There is no evidence to support that Adderall is the only medication choice available to treat the enrollee's condition.

The Michigan Insurance Code Section 3406o [requires] exceptions from [an insurer's] formulary limitations when a non-formulary alternative is medically necessary. The enrollee does not meet the criteria as Adderall does have a generic alternative, despite the fact that the enrollee experienced an untoward side effect from one of the generic brands. There is not any documentation

submitted for review that the patient exhausted other covered medications, generic or brand name if a generic was not available. Therefore, the requested brand name prescription medication Adderall XR is not medically necessary.

[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 recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15). The Director can discern no reason why the IRO's recommendation should be rejected in the present case.

Based on the IRO analysis and the absence of evidence that the Petitioner has fully explored the efficacy of other similar, generic, covered drugs, the Director finds that Adderall XR is not, at present, a drug for which BCBSM must provide coverage.

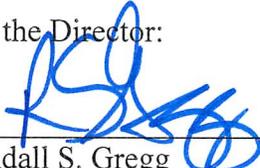
V. ORDER

The Director upholds BCBSM's final adverse determination of December 25, 2014. BCBSM is not required to provide prescription drug coverage for brand name Adderall XR.

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