

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. 153632-001

Blue Cross Blue Shield of Michigan,  
Respondent.

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Issued and entered  
this 13<sup>th</sup> day of June 2016  
by Randall S. Gregg  
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner)<sup>1</sup> was denied coverage for a prescription drug by her health insurer, Blue Cross Blue Shield of Michigan (BCBSM).

On May 16, 2016, ██████████, who was who was authorized by the Petitioner's mother to represent the Petitioner, 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 May 23, 2016.

The Petitioner receives 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 responded on May 25, 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 June 6, 2016.

II. FACTUAL BACKGROUND

The Petitioner's drug benefit is described in BCBSM's *Preferred Rx Program Certificate SG* (the certificate).

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<sup>1</sup> The Petitioner is a minor, born October 4, 2003.

The Petitioner has attention deficit hyperactivity disorder (ADHD). Her physician asked BCBSM to cover the prescription drug Focalin XR (dexamethylphenidate hydrochloride) to treat her condition.

BCBSM denied the request, saying the drug is not on its drug formulary and is therefore not a covered benefit. The Petitioner's mother 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 May 2, 2016. The Petitioner now seeks a review of that final adverse determination from the Director.

### III. ISSUE

Did BCBSM correctly deny coverage for the prescription drug Focalin XR?

### IV. ANALYSIS

#### BCBSM's Argument

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

. . . After review, I confirmed the denial must be maintained. Dexmethylphenidate Hcl is excluded from coverage under your drug plan.

You have prescription drug coverage under the *Preferred Rx Program Certificate SG*. As indicated in **Section 3: Prescription Drugs Not Covered** (pages 17-20) of your *Certificate*, your plan does not pay for anything other than covered drugs and services. The covered drugs for your group's plan are listed in the BCBSM Custom Select Drug List. . . . As Dexmethylphenidate Hcl is not listed on the Drug List, it is not covered by your plan.

To ensure all possible consideration was given, a clinical Pharmacist, RPh reviewed the submitted documentation and determined the following:

Documents reviewed: appeal request, initial case, conference notes, and additional clinical documentation received (chart notes pages 4-8). The requested medication is excluded from coverage under your Custom Select drug plan. Covered stimulant alternatives include generic Focalin immediate release (dexamethylphenidate) and Vyvanse. Covered non-stimulant alternatives include generic Kapvay (clonidine ER), and Strattera. For a complete list of covered alternatives please refer to your Custom Select drug list.

Therefore, preauthorization for Dexmethylphenidate Hcl could not be approved. If this prescription is filled, you will be liable for all charges.

Petitioner's Argument

On the external review request form, the Petitioner's authorized representative wrote:

[The Petitioner] took Metadate CD 20 mg but the medication was discontinued after one week due to nausea and [low] appetite.

When she took Adderall XR 10 mg she was jittery and nervous and had no appetite. She is not able to swallow pills. When she took Focalin XR her ADHD symptoms were well controlled. . . .

In a progress noted dated March 25, 2016, Petitioner's physician explained:

[The Petitioner] was placed on a trial of Metadate CD 20 mg in the morning for treatment of her ADHD symptoms. She took that medication for one week and treatment was discontinued due to nausea and decreased appetite. I recommended a trial of Focalin XR but the medication was not covered by her insurance and her mother decided to pay out-of-pocket to try it. [The Petitioner] has been taking Focalin XR 20 mg in the morning on school days and 10 mg in the morning on the weekends. She has done quite well on the medication. [She] has been more calm and attentive in class. She is completing her work and her grades have improved. [She] is also more attentive to tasks at home and she does not require frequent reminders. She is making her bed every day before school and she has organized her closet. No medication-related side effects have been reported. Her appetite is not affected by the medication and she does not have any difficulty falling asleep at night. No motor or vocal tics have been noted. She denied any symptoms of anxiety or depression.

Director's Review

BCBSM denied authorization for the drug Focalin XR (dexamethylphenidate Hcl) because it is not included in the Petitioner's drug formulary (called the "Custom Select Drug List"). However, a health plan that limits coverage for drugs to those on a formulary must provide an exception 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:

\* \* \*

(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.

To determine whether Focalin XR is a medically necessary and appropriate alternative to the drugs that are on the formulary to treat the Petitioner's condition, the question 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 board certified in child neurology, has been in active practice for more than 18 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following recommendation and analysis:

**Recommended Decision:**

The MAXIMUS physician consultant determined that Focalin XR (dexamethylphenidate Hcl) is medically necessary for treatment of the member's condition.

**Rationale:**

\* \* \*

The results of the consultant's review indicate that this case involves a 12 year-old female who has a history of attention deficit hyperactivity disorder, cerebral palsy and developmental delay. At issue in this appeal is whether Focalin XR (dexamethylphenidate Hcl) is medically necessary for treatment of the member's condition.

The medical records provided for review clearly document that the member had an efficacious response to Focalin XR. These medical records also detail her adverse responses to other stimulant medications with different formulations or chemical structures. The MAXIMUS physician consultant explained that sometimes individual responses to stimulants are not equally efficacious despite the fact that all stimulants medications act by similar mechanism. The physician consultant also explained that requiring the member to try other chemically dissimilar drugs is not consistent with best medical practice. The consultant indicated that in this case, the nonformulary alternative Focalin XR is medically necessary and appropriate for treatment of the member's condition.

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,

adopts the recommendation and finds that Focalin XR is medically necessary and appropriate to treat the Petitioner.

**V. ORDER**

The Director reverses BCBSM's May 2, 2016 final adverse determination. BCBSM shall immediately authorize coverage for the prescription drug Focalin XR for the Petitioner. MCL 550.1911 (17). Further, BCBSM shall, within seven days of authorizing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the department of Insurance and Financial Services, Health Care Appeals Section, at this toll free telephone number (877) 999-6442.

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 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:



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Randall S. Gregg  
Special Deputy Director