

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. 153473-001

Priority Health Insurance Company,
Respondent.

Issued and entered
this 31st day of May 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On April 29, 2016, ██████████ (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.*

The Petitioner receives health care benefits through an individual plan underwritten by Priority Health Insurance Company (Priority). The Director notified Priority of the external review request and asked for the information it used to make its final adverse determination. After a preliminary review of the material submitted, the Director accepted the request on May 6, 2016. Priority provided its response on May 10, 2016.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation to the Director on May 20, 2016.

II. FACTUAL BACKGROUND

The Petitioner is a 23 year-old male with a diagnosis of attention deficit hyperactivity disorder (ADHD) and cerebral palsy. He was started on Focalin XR in September 2015 to get a greater impact from Ritalin LA. His physician increased his dosage and prescribed Focalin XR 160 mg each morning and 80 mg at bedtime, for a total of 240 mg daily. Priority denied coverage for Focalin at the dosage of 240 mg per day on the basis that it limits coverage of this drug to 50 mg daily; and the Petitioner provided no documentation to support that the requested

dosage was medically necessary for the treatment of his condition.

The Petitioner's mother appealed the denial through Priority's internal grievance process. At the conclusion of that process Priority issued a final adverse determination dated March 25, 2016, affirming its decision. The Petitioner now seeks a review of that final adverse determination by the Director.

III. ISSUE

Is Priority required to cover the prescription drug Focalin XR at the daily dosage of 240 mg for the treatment of the Petitioner's condition?

IV. ANALYSIS

Petitioner's Argument

In the external review request, the Petitioner wrote:

Priority Health will not fill the prescribed doses of Focalin XR of 8 capsules a day. This dosage has been used over 10 years and was covered by preceding insurance with a tier override.

I want to receive coverage for all of my drugs at the prescribed dosage. Focalin XR is the drug being denied at this time by Priority.

In a letter to Dr. [REDACTED] dated September 19, 2005 regarding the initiation of Focalin, Petitioner's neurologist explained:

I saw [Petitioner] today in the company of his parents... for an established office visit. [Petitioner] is now on Ritalin LA 40 mg. cap, sig: 4 cap. (160 mg.) p.o. q. 6:00 a.m. The Ritalin has had a wondrous effect on academic performance this year. He has just matriculated in 7th grade at [REDACTED] Middle School in the homeroom of Mrs. [REDACTED], special education teacher. He is taking Band, enrichment including economics, art and music appreciation, exploration of both physical conditioning and career planning, Algebra, English, and Social Studies, which is really American Geography and Natural Resources. He is doing quite well. His appointment today is accompanied by a note from one of his teachers, who had him in 4th grade. She is very pleased with his demeanor, attention to detail, and his efforts to perform. He is doing fairly well in Algebra, which is surprising. It does buttress the parents' arguments that last year he was bored by the paucity of challenge.

The Ritalin is given at 6 a.m., and the effect is probably exhausted between 3 and 4 p.m., when he sits down to do his homework. He sits down to do homework in the presence of his parents and under their direct parental supervision. It takes a lot of governance and chiding. We have talked about trying to get greater impact

from the Ritalin LA, and I have recommended changing to Focalin XR for that reason. He also needs a boost before he sits down and works. We could use standard Focalin for that task. Again, the advantage of Focalin over Ritalin is that Focalin is purified Ritalin so we would be able to dispense with 3 of the isomers and all of their side effects. We ought to be able to get a better attentional bang for our medication buck using Focalin, mg. per mg. when compared to Ritalin. He remains on ProVigil 200 mg. tab., sig: 1 tab. at 6 a.m. We see no reason to change that. He is becoming a bit more social. He is more aware of social strictures and social expectations. He is planning better. He continues on his physical conditioning program. He and his father go to the Health Fitness place three times a week, where [Petitioner] does 10 reps, 3x on each of 5 machines, and then runs a bit. His physical skills are improving.

Petitioner's medical records notes also notes changes in his dosing of Focalin. Records dated April 4, 2006 show he was changed to the requested dosage. The Petitioner's mother also indicates the requested dosage is medically necessary and prescribed by his doctors noting that prior to beginning this medication he struggled in school. Since he began using taking Focalin over 10 years ago, he has successfully completed high school and earned a college degree. She argues that BCBSM is required to cover this drug at the prescribed dosage.

Priority's Argument

In its final adverse determination, Priority told the Petitioner:

Decision:

Uphold denial-requested coverage will not be provided as Focalin XR 20 mg has a quantity limitation of 1 capsule per day. Coverage of dexamethylphenidate products, including Focalin, is limited to a maximum daily dose of 50 mg as outlined in the Priority Health Approved Drug List, Pharmacy Policy for Drug coverage limits, and MyPriority POS Agreement. In addition, Priority Health has not been provided with sound and appropriate guidelines supporting usage of more than 50 mg of dexamethylphenidate products daily.

The Appeals Committee understands that [the Petitioner] has been on these medications for a number of years to treat his condition and they have proven to be effective for him, however, the committee did not agree that an exception to the coverage criteria was appropriate in this situation.

Director's Review

Priority denied Focalin XR at the dosage of 240 mg total per day on the basis that its Approved Drug List limits coverage of Focalin to a 31 day supply of 50 mg per day, therefore, a higher dosage is not medically necessary. Priority also noted according to the FDA approved manufacturer's label, "the maximum recommended dose is 20 mg/day. However, Section 34060 of the Michigan Insurance Code, MCL 500.34060, requires an insurer to provide coverage for a

nonformulary drug when it is medically necessary and appropriate.

The question of whether Focalin XR at a dosage of 240 mg a day is medically necessary and appropriate alternative for treatment of the Petitioner's condition was presented to an independent review organization (IRO) for analysis and a recommendation 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 Psychiatry and is in active practice. The IRO report included the following analysis and recommendation:

The enrollee was being prescribed Focalin XR for treatment of his diagnosed ADHD without hyperactivity. As per Food and Drug Administration (FDA) guidelines, the off-label maximum dose is 50 mg.

The prescription drug Focalin XR at the dosage of 240 mg daily is not medically necessary for this enrollee due to the fact that Focalin XR is a non-preferred brand with a quantity limit for thirty days, maximum daily dose of 50 mg and age restriction for ages greater than four. Section 3406o of the Michigan Insurance Code provide for exceptions from the formulary limitations when a nonformulary alternative is a medically necessary and appropriate alternative.

According to the American Academy of Child and Adolescent Psychiatry (AACAP) Practice parameters "patient's treatment should take into account that ADHD is a chronic disorder and may consist of psychopharmacology and/or behavioral therapy. Stimulants are highly efficacious in the treatment of ADHD. Single daily dosing is associated with greater compliance for all types of medication and long-acting Methylphenidate (MPH) may improve driving performance in adolescents relative to short-acting MPH. The physician is free to choose any of the 2 stimulant types (MPH-Focalin XR), because evidence suggests the two are equally efficacious in treatment of ADHD. The typical dosing for Focalin XR off-label maximum daily dosing is 50 mg. There have not been any studies examining the efficacy of doses of MPH/amphetamine in adolescents, of more than 60 mg/day or have there been studies examining the efficacy of doses of 72 mg/day of Concerta. If a patient with ADHD has been symptom free for at least 1 year, then inquiries should be made about whether the patient and family still think the medication provides a benefit."

Few long-term studies, longer than 24 months on use of stimulants for the management of ADHD exist, therefore the precise long-term effects, adverse or positive, remain unknown. They were treated with Focalin XR and placebo. The conclusion of the study was that once daily dosing of 30 or 40 mg of Focalin XR is safe and efficacious for treatment of adult ADHD.

As a conclusion of all the reviewed materials

1. There is no clear guidelines for continuous treatment of adults previously diagnosed with ADHD as children.

2. The consensus seems to be re-evaluation of adult ADHD and further need for treatment.
3. Finally, if treatment is deemed necessary there are no studies proving that more than 30-40, up to 50 mg daily (for off-label uses) are more efficacious and/or safe in adult ADHD treatment. [References omitted]

Recommendation:

It is the recommendation of this reviewer that the denial issued by [Priority] for Focalin XR at the dosage of 240 mg total per day 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 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 why the IRO's recommendation should be rejected in this case, finds that Focalin XR at the dosage of 240 mg total per day is not medically necessary for the treatment of the Petitioner's condition and is therefore not a benefit under the terms of the certificate.

V. ORDER

The Director upholds Priority's final adverse determination of March 25, 2016. Priority is not required to cover Focalin XR at the dosage of 240 mg per day.

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