

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. 154313-001

Health Alliance Plan of Michigan
Respondent

Issued and entered
this 20th day of July 2016
by Joseph A. Garcia
Special Deputy Director

ORDER

I. BACKGROUND

On June 24, 2016, ██████████, authorized representative of ██████████ (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, including prescription drug coverage, through Health Alliance Plan of Michigan (HAP), a health maintenance organization. The Petitioner's benefits are defined in HAP's *Group Subscriber Contract*.

The Director notified HAP of the external review request and asked for the information used to make its final adverse determination. HAP provided its response on June 30, 2016. After a preliminary review of the information submitted by the parties, the Director accepted the request on July 5, 2016.

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 July 15, 2016.

I. FACTUAL BACKGROUND

The Petitioner, who is ten years old, has attention deficit hyperactivity disorder (ADHD) and autism spectrum disorder. His physician prescribed the drug Ritalin LA, 20 mg daily, to treat the Petitioner's ADHD. HAP was asked to provide coverage for the drug. HAP denied the request.

Petitioner's authorized representative appealed the denial through HAP's internal grievance process. At the conclusion of that process, HAP issued a final adverse determination dated June 16, 2016 affirming its denial. The Petitioner now seeks the Director's review of that adverse determination.

III. ISSUE

Did HAP properly deny prescription drug coverage for Ritalin LA?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination, HAP wrote:

Based on all available evidence, previous decisions and your medication history, Pharmacy Care Management recommends upholding the denial for Ritalin LA. Ritalin LA (methylphenidate capsule, biphasic release) is a medication used to treat attention-deficit hyperactivity disorder (ADHD) and it is not listed on your Formulary (non-formulary). Your formulary policy states that a formulary exception may be requested when all formulary options have been tried and failed, or with documented contraindication for use of all formulary options. However, you have not tried all formulary options.

Your formulary provides coverage for multiple other medications used to treat attention-deficit hyperactivity disorder (ADHD). A complete list of options can be found under the sections titled "Central Nervous System Agents – Anorexigenic agents and respiratory and CNS stimulants – Amphetamines" and "Respiratory and CNS Stimulants." The information provided to HAP indicates that you have tried and failed Strattera, Intuniv and Ritalin in the past, but there was no indication of use of any other formulary options. Therefore, since you have not tried and failed all formulary options to treat ADHD, nor do you have any contraindications to use of formulary medications, criteria for a formulary exception has not been met and the original denial is upheld.

Petitioner's Argument

In a letter dated June 22, 2016, the Petitioner's representative, a nurse in the office of the Petitioner's doctor, wrote:

New information, which was not noted on the initial appeal letter, has been received. In the past, the patient has taken higher strength Ritalin and Adderall which both caused tics. Straterra alone was ineffective, patient was unable to stay focused. The lower strength Ritalin and Straterra has

been effective. [The patient] also takes Intuniv. According to the doctor, the patient is very sensitive to medications and the patient has tolerated the medication cross-titration well, he did not have any worsening of symptoms after being restarted on stimulant, he continues to be on Strattera as a bridging strategy and so far the medications have helped him in the classroom as well as at home without causing any side effects. He is able to pay attention in his class and tolerates transitions well, school has introduced several sensory strategies to help him in times of distress and he responds well to the positive distractions. The patient has been taking Ritalin since 2/2016 and has had good symptom control. According to Rite Aid, patient's pharmacy, claims were paid through MI Health, which has now been terminated. The patient has been without medication for a couple of weeks now, and needs his medication.

Director's Review

HAP denied coverage for the drug Ritalin LA because it is not included on its approved drug list (its formulary) and because the Petitioner has not tried all HAP's approved ADHD drugs. HAP does have an exception process and its criteria are described in HAP's July 1, 2016 Commercial Formulary (pages 3-4):

When your drug is not listed on the Formulary it is considered non-formulary. You or your doctor can ask us to make an exception and cover your drug and one of HAP clinical specialists will evaluate if the medication will be covered by your plan. However it is best to first discuss with your doctor or pharmacist if one of the formulary alternatives will work for you.

The Michigan Insurance Code includes a similar provision which requires health insurers to provide coverage for nonformulary drugs under some circumstances. Section 3406o of the 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 question of whether Ritalin LA is a medically necessary and appropriate alternative to treat the Petitioner was presented by the Director 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 who is certified by the American Board of Psychiatry and Neurology with a subspecialty in child and adolescent psychiatry. The reviewer is a clinical assistant professor of psychiatry and human behavior at a medical college and is published in peer reviewed medical literature. The IRO physician's report included the following analysis and recommendation:

Clinical Rationale for the Decision:

A patient with ADHD requires the standard of care of medication management in the form of either mix amphetamine salts, methylphenidate derivatives, or other non-stimulant medication options ... [M]ethylphenidate derivatives are a standard treatment of ADHD and may be used as first line or second line after a medication based on amphetamine salts is used. Methylphenidate derivatives are considered equally effective for initial treatment of ADHD, and while individuals may not initially respond to Concerta, Vyvanse, or generic Focalin XR but would respond to Ritalin LA, standard of care does not acknowledge one is likely to be more effective than another.

The Michigan Insurance Code [requires insurers to]...provide exceptions from the formulary limitations when a non-formulary alternative is medically necessary and an appropriate alternative. This is not the case in this clinical scenario. The non-formulary alternative Ritalin LA was not medically necessary given that formulary alternatives are clinically appropriate in this situation, specifically generic Concerta, Vyvanse, and generic Focalin XR.

The enrollee's condition of ADHD requires the standard of care of medication management with either mix amphetamine salts, methylphenidate derivatives, or other non-stimulant medication options. Several methylphenidate derivatives, such as generic Concerta, Vyvanse, and generic Focalin XR, were available and on formulary for this enrollee at the time of the visit. There was no clinical justification to choose Ritalin LA prior to trying these options.

The HAP notes the enrollee was not prescribed Ritalin, but Ritalin LA. Per the documentation submitted for review, there is no clinical justification as to why Ritalin versus Ritalin LA should be used, and it appears these medications were documented interchangeably despite being two different medications. In the March 22, 2016 physician progress note, it states Ritalin was increased to 20 mg daily, yet it was later noted that Ritalin LA 20 mg would be prescribed. It appears these medications were again being discussed interchangeably.

The prescription medication Ritalin LA is not medically necessary for this enrollee. Reasonable medical analogues were available on formulary,

such as generic Concerta, generic Focalin XR, and Vyvanse, and there is no reason to clinically suspect that they would be less effective than Ritalin LA. Therefore, for the reasons noted above, Ritalin LA is not medically necessary for the treatment of the enrollee's condition.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Health Alliance Plan of Michigan for the prescription drug Ritalin 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 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 can discern no reason why the IRO's analysis and recommendation should be rejected. In addition, the IRO's recommendation is not contrary to any provision of HAP's *Group Subscriber Contract*. See MCL 550.1911(15). The Director accepts the IRO's recommendation and finds the prescription drug Ritalin LA is not medically necessary to treat the Petitioner's condition and is, therefore, not a covered benefit under the terms of the contract.

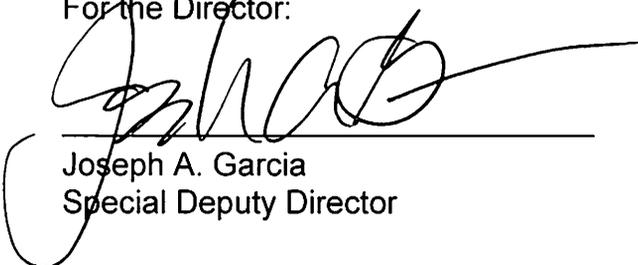
V. ORDER

The Director upholds Health Alliance Plan of Michigan's June 16, 2016 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 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:



Joseph A. Garcia
Special Deputy Director