

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. 151922-001

Priority Health Insurance Company,
Respondent.

Issued and entered
this 14th day of March 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

██████████ (Petitioner) was denied coverage for a sedative used to treat insomnia by her health plan, Priority Health (Priority).

On January 27, 2016, 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.*

The Petitioner receives health care benefits, including prescription drug coverage, from Priority, a health maintenance organization. The Director immediately notified Priority of the external review request and asked for the information it used to make its final adverse determination. Priority responded on February 1, 2016. On February 3, 2016, after a preliminary review of the material submitted, the Director accepted the request.

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 February 19, 2016.

II. FACTUAL BACKGROUND

The Petitioner has chronic insomnia. Her physician prescribed Ambien 10 milligram

(mg) tablets, 2 tablets to be taken at bedtime. Priority would not approve this dosage of Ambien, saying it exceeds the quantity limitation and is not consistent with Food and Drug Administration (FDA) labeling.

The Petitioner appealed the denial through Priority's internal grievance process. At the conclusion of that process, Priority issued a final adverse determination dated January 15, 2016, upholding its denial. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did Priority properly deny the Petitioner's request for the dosage of Ambien?

IV. ANALYSIS

Petitioner's Argument

In her request for an external review the Petitioner said:

Requesting Ambien 10mg - 2 @ bedtime

Have taken several other meds - none work. Doctor wrote a script for Ambien 10mg -2 at bedtime. Fall asleep gently, wake totally refreshed and not groggy. Other meds - 2 to 3 hrs to fall asleep - dozed 2-3 hours at a time. No "real" sleep. Have multiple replacement parts, a shoulder that needs replacing, severe arthritis since age 28. I am now [REDACTED]. Very bad problems sleeping - also nerve damage in right calf and foot due to motorcycle accident. Will get physically ill without sleep. Pharmacy will fill script if I pay for it and yes they also follow FDA guidelines. Priority Health has a pharmacy "department." I deal with a "real" pharmacy and a doctor who knows me as a patient for many years and understands.

Respondent's Argument

In its final adverse determination, Priority said:

Issue:

[The Petitioner] is requesting coverage of Ambien 10 mg, 2 tablets at bedtime, in lieu of the maximum quantity limitation of 31 tablets per 31 days.

[The Petitioner] states: I had been taking Ambien and when you guys refused to fill it, my doctor tried a different medication. I take 2 at bedtime and 2-3 hours later I am still awake so I do not get much sleep at all. The Ambien works better and is cheaper than the other medication. I have had insomnia for many years

and cannot sleep without a sleeping aid. Without sleep I get physically ill. My doctor is not writing an illegal prescription and the pharmacy, who follows FDA guidelines, has no problem filling it.

Decision:

Uphold denial - requested coverage will not be provided. Specifically, Ambien is limited to a maximum quantity of 31 tablets per 31 days as outlined in the Priority Health Approved Drug list and Certificate of Coverage. In addition, the FDA Label for Ambien indicates the total dose should not exceed 10 mg daily.

The Appeal Committee noted that [the Petitioner] states this dosage of Ambien has proven to be effective for her, however, the committee did not agree that an exception to the coverage criteria was appropriate in this situation.

* * *

The FDA Label for Ambien states:

2 DOSAGE AND ADMINISTRATION

2.1 Dosage in Adults

Use the lowest effective dose for the patient. The recommended initial dose is 5 mg for women and either 5 or 10 mg for men, taken only once per night immediately before bedtime with at least 7-8 hours remaining before the planned time of awakening. If the 5 mg dose is not effective, the dose can be increased to 10 mg. In some patients, the higher morning blood levels following use of the 10 mg dose increase the risk of next day impairment of driving and other activities that require full alertness [*see Warnings and Precautions (5.1)*]. The total dose of AMBIEN should not exceed 10 mg once daily immediately before bedtime.

The recommended initial doses for women and men are different because zolpidem¹ clearance is lower in women.

Director's Review

Priority declined to approve coverage for Ambien 10 mg, two tablets taken at bedtime, because its drug formulary that limits coverage of Ambien 10 mg tablets to 31 per 31 days. That limitation was based on Food and Drug Administration's label for Ambien which says "the total dose of AMBIEN should not exceed 10 mg once daily immediately before bedtime."

¹ Zolpidem is the generic version of Ambien.

To help the Director answer the question of whether the requested dosage of Ambien was medically necessary, the case was assigned 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 certified by the American Board of Family Practice with a subspecialty in acute care and urgent care; is a member of the American Academy of Family Physicians; and is in active clinical practice. The IRO reviewer's report included the following analysis and conclusion:

Reviewer's Decision:

It is the determination of this reviewer that the Ambien 10 mg, two tablets at bedtime is not medically necessary for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

The Federal Food and drug Administration (FDA) product brochure of Ambien indicates that the typical dosage for a female on Ambien is five (5) mg at night time. It can be increased to ten (10) mg at night if needed. The product information recommended against long-term use of Ambien at twenty (20) mg per night dosage. . . .

The documentation submitted for review shows the enrollee has previously been on Ambien CR, Restoril, and trazodone. It is apparent that this enrollee is indeed having significant insomnia problems that are distressing her greatly. But, the requested dosage of Ambien is too high, and the medication is only for short-term use. Increasing the dose of the enrollee's Ambien to a dose above FDA recommendations would not be beneficial in the long run, and may well produce additional side effects. Therefore, based on the documentation submitted for review . . . and FDA recommendations, the Ambien 10 mg, two (2) tablets at bedtime is not medically necessary for this enrollee.

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 because it is based on extensive experience, expertise, and professional judgment. 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 Director also finds that 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 in this case, finds that the requested dosage of Ambien 10mg is not medically necessary and is therefore not a covered benefit.²

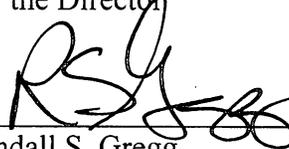
V. ORDER

The Director upholds Priority's January 15, 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



Randall S. Gregg
Special Deputy Director

² Section 3406o of the Insurance Code, MCL 500.3406o, requires health maintenance organizations to make exceptions to limitations in their formularies under certain circumstances. However, that section does not require an exception when a requested dosage exceeds the recommendation of the Food and Drug Administration.