

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. 153172-001

Alliance Health and Life Insurance Company
Respondent

Issued and entered
this 7th day of May 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On April 11, 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 request for review concerns a denial of coverage by the Petitioner's insurer for a drug prescribed by her physician. The Petitioner receives prescription drug benefits through an individual plan underwritten by Alliance Health and Life Insurance Company (Alliance). The Director notified Alliance of the external review request and asked for the information used to make its final adverse determination. Alliance provided its response on April 14, 2016. The Director accepted the request for review on April 18 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 April 28, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 63 years old and has hypertension and diabetes mellitus. As a part of her treatment, her doctor prescribed the brand name drug Atacand HCT. Alliance denied coverage for the drug. The Petitioner appealed the denial through Alliance's internal grievance process. At the conclusion of that process, Alliance affirmed its decision in a final adverse determination dated March 28, 2016. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Did Alliance correctly deny the Petitioner coverage for the prescription drug Atacand HCTZ ?

IV. ANALYSIS

Alliance's Argument

In its final adverse determination Alliance wrote:

After considering all available evidence, previous decisions and your medication history, the recommendation is to uphold the denial for Atacand HCTZ. Atacand HCTZ is non-formulary medication. According to Criteria for coverage of Dispense as Written (DAW) Medications, coverage may be provided when there is evidence in the patient's medical record that all formulary, preferred, alternatives to treat the medical condition have not been effective or caused adverse effects that are not likely to be caused by the requested brand medication as well. Also, in accordance with the goals of FDA Medwatch Program to improve the safety of pharmaceuticals by documenting important safety issues, a Medwatch form must be submitted to the FDA that documents adverse events suffered by the member while taking generic medication. Documentation must show failure of the generic formulation of the requested brand name drug and failure of all generic formulations in the same medication class and failure of all formulary options indicated to treat the same medical condition. Atacand HCTZ belongs to a class of medications called Angiotensin II Receptor Antagonists (ARBs) used to treat hypertension and is the brand name medication for generic candesartan-HCTZ.

Based on the information provided and your prescription claims record, you have only tried the following generic ARBs: candesartan and valsartan. You have not tried and failed all formulary ARBs. Additionally, the Formulary provides coverage for numerous other medications classes to treat hypertension (examples: calcium channel blockers, angiotensin-converting enzyme inhibitors, beta-blockers, central alpha-agonists, direct vasodilators, aldosterone antagonists) that the member has not yet tried. Criteria for coverage of brand name medication have not been met and medical necessity has not been demonstrated. Therefore, the appeal request has been denied.

Petitioner's Argument

In the request for external review, the Petitioner wrote:

Requesting coverage for the prescription drug Atacand HCTZ tab. Alternative medications used to treat hypertension cause adverse effects such as, incontinence, severe muscle ache/pain, severe abdominal pain, constipation, headaches, swelling of joints, legs. All effects plus no regulation of blood pressure. Continued use of alternate meds caused emergency care.

In a letter dated March 24, 2016, Petitioner's physician noted the previous medications she has taken and the side effects experienced:

Propranolol HCL 40 mg BID. While on the medication the patient had uncontrollable weight gain of over 10 pounds and once stopped the medication the patient's weight returned to the patient's normal weight.

Amiodipine Besylate 5 mg QD. The patient had abdominal pain and constant headaches while on the medication for over 1 month.

Valsartain HCTZ 106-2.5 QD. The patient had nausea and intermittent dizziness for over 1 month while on the medication.

Candesartan [Ciexeill]. When patient tried to use the generic for Atacand she had difficulty having any bowel movements and abdominal pain which required the patient to be admitted to the hospital.

Director's Review

Alliance denied coverage for the drug Atacand HCT because it is not included on its drug formulary and because the Petitioner has not tried all the blood pressure drugs that are listed on its formulary. The Petitioner asked for an exception but Alliance determined that she did not meet medical necessity criteria. The question of whether Atacand HCT is a medically necessary and appropriate drug to treat the Petitioner 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 reviewer is a physician in active practice who is board certified in family practice with a subspecialty in acute care and urgent care. The IRO report included the following analysis and recommendation:

The enrollee is hypertensive and diabetic. Individuals with diabetes have improvement in terms of diabetic outcomes when they are taking an angiotensin converting enzyme (ACE) inhibitor drug or an angiotensin receptor blocker. Therefore, the choice of candesartan/HCTZ is reasonable.

* * *

According to the FDA: "When a generic drug product is approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality purity and potency....Generic drugs are required to have the same active ingredient, strength, dosage form, and route of administration as the brand name product....The generic drug manufacturer must prove its drug is the same as (bioequivalent) the brand name drug....Through review of bioequivalence data, FDA ensures that this generic product performs the same as its respective brand name product. This standard applies to all generic drugs, whether immediate or controlled release...."

In this case, Atacand HCT is nonformulary. There is no substantial difference between Atacand HCT and its generic formulation candesartan/HCTZ. The bioequivalence should be equal. There is no evidence that name brand Atacand HCT would be more beneficial than the identical and much less expensive

generic version candesartan/HCTZ. Therefore, the brand name prescription drug Atacand HCT is not medically necessary.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Alliance Health and Life Insurance for the brand name prescription drug Atacand HCT Tab 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'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 can discern no reason why the IRO's analysis should be rejected in the present case. In addition, the Director notes the substantial number of other drugs on Alliance's formulary which are available to treat the Petitioner's condition. Consequently, the Director finds that Atacand HCT is not medically necessary to treat the Petitioner.

V. ORDER

The Director upholds Alliance's March 28, 2016 final adverse determination. Alliance is not required to cover the Petitioner's Atacand HCT prescription.

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



Randall S. Gregg
Special Deputy Director