

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████
Petitioner

v

Health Alliance Plan of Michigan
Respondent

File No. 150384-001

Issued and entered
this 16th day of November 2015
by **Joseph A. Garcia**
Special Deputy Director

ORDER

I. BACKGROUND

On October 16, 2015, Dr. ██████████, 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 prescription drug coverage from Health Alliance Plan of Michigan (HAP), a health maintenance organization. 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 October 19, 2015. On October 23, 2015, 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 November 4, 2015.

II. FACTUAL BACKGROUND

The Petitioner is 64 years old and has a history of back, neck, and shoulder pain. Her doctor prescribed the prescription drug Subsys spray for treatment of her pain. HAP denied coverage.

The Petitioner appealed the denial through HAP's internal grievance process. At the conclusion of that process, on September 10, 2015, HAP issued a final adverse determination affirming its denial. The Petitioner now seeks from the Director a review of the coverage denial.

III. ISSUE

Did HAP properly deny prescription drug coverage for Subsys?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination, HAP wrote:

Subsys is a non-formulary medication. It contains the active ingredient of Fentanyl, and is used for "breakthrough" severe pain in patients who are uncontrolled on long acting pain medications. The HAP formulary provides coverage, with prior authorization, for generic Actiq (Fentanyl lozenge) for use in breakthrough pain in patients who are uncontrolled with a long-acting Fentanyl patch, and have failed prior therapies with other long-acting and short-acting opioid pain medications (i.e. Morphine Sulfate, Hydromorphone, or Oxycodone). Per the HAP Formulary Policy, members must use formulary medications for an appropriate length of time and demonstrate that these medications have either been ineffective or have caused significant and unacceptable side effects, before they may ask for an exception for coverage of a non-formulary medication.

According to the claims records and office notes, you have used Methadone and Percocet. There are no claims records for long-acting pain medications such as Fentanyl patch, Morphine ER or Oxycodone ER. Opioid medications can be titrated up to higher doses, to provide greater pain relief. Dr. Pompy states that you have difficulty swallowing and tolerating medications by mouth. However, based on your claims records, you consistently take many different oral medications for various medical conditions.

Petitioner's Argument

In a September 3, 2015, letter filed with the request for an external view the Petitioner's doctor stated:

In my clinical judgement, the requested prescription therapy (Subsys spray) will provide a significant clinical relief for [Petitioner] as round the clock pain relief. The requested prescription is medically necessary and appropriate treatment for

the patient's many medical conditions. She has tried and failed numerous medications with little or no relief including but not limited to: Percocet and Methadone. I urge you to provide coverage at this time. Providing coverage could limit the amount of additional office visits, ER visits and procedures, which will help control health cost.

Director's Review

HAP denied authorization for the drug Subsys since it was not included in its list of covered drugs (HAP's formulary). However, both HAP's formulary and Michigan law (section 3406o of the Michigan Insurance Code, MCL 500.3406o) provide for an exception from the formulary requirement when a nonformulary alternative is a medically necessary and appropriate alternative. The question of whether Subsys is medically necessary for 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 physician reviewer is a physician who is board certified in anesthesiology and pain management and has been in active practice for more than 12 years. The IRO reviewer's report included the following analysis and conclusion:

Subsys (sub-lingual spray Fentanyl) is indicated only for the treatment of breakthrough pain for cancer....[T]he use of Subsys for this member would be off label....[T]he member has not had a trial of long acting agents at high dose....[A] trial of a long acting agent and an appropriate breakthrough medication would be consistent with good medical practice....[T]he member has also not had any documented trials of medications that are approved for the treatment of neuropathic pain.

Pursuant to the information set forth above and available documentation... Subsys is not a medically necessary and appropriate alternative 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. The Director can discern no reason why the IRO's recommendation should be rejected in the present case.

V. ORDER

The Director upholds HAP's September 10, 2015 final adverse determination. HAP is not required to provide the Petitioner with coverage for the prescription drug Subsys.

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 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

A handwritten signature in black ink, appearing to read "Joseph A. Garcia", written over a horizontal line.

Joseph A. Garcia
Special Deputy Director