

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. 150963-001

Priority Health
Respondent

Issued and entered
this 21st day of December 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On November 19, 2015, ██████████ (Petitioner) filed a request for external review with the Director of Insurance and Financial Services under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care and prescription drug benefits under an individual plan through Priority Health, a health maintenance organization. The Petitioner's benefits are defined in Priority Health's *MyPriority HSA POS Agreement* and the *MyPriority HSA - Gold Schedule of Copayments and Deductibles*.

The Director notified Priority Health of the request and asked for the information used to make its final adverse determination. Priority Health furnished the requested information on November 24, 2015. After a preliminary review of the material submitted, the Director accepted the request on November 30, 2015.

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 December 15, 2015.

II. FACTUAL BACKGROUND

The Petitioner has multiple sclerosis. His physician recommended the prescription drug Tysabri and requested that Priority Health prior approve coverage for its use. Priority Health denied the request. The Petitioner appealed the denial through Priority Health's internal

grievance process. Priority Health affirmed its denial in a final adverse determination dated September 24, 2015. The Petitioner now seeks a review of this denial from the Director.

III. ISSUE

Did Priority Health correctly deny the Petitioner's request for prior approval of the prescription drug Tysabri?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination, Priority Health provided this explanation for its denial of coverage:

[Petitioner] does not currently meet the medical criteria or coverage of Tysabri. Specifically, medical records reviewed do not indicate [Petitioner] has tried Avonex or Gilenya.

Priority Health states that the criteria for coverage for Tysabri are found in its Medical Prior Authorization Form which provides:

Before this drug is covered, the patient must meet all of the following requirements:

1. Age 18 years or older
2. One of the following diagnoses and completion of applicable step therapy:
 - Relapsing-remitting multiple sclerosis with a documented therapeutic trial with two of the following: Avonex, Gilenya, and Tecfidera.
 - Moderate to severe active Crohn's disease with a documented therapeutic trial with Humira and Remicade

Petitioner's Argument

In a letter dated September 21, 2015, the Petitioner's physician wrote:

[Petitioner] has been a patient of my office for over a year, and has been diagnosed with relapsing and remitting multiple sclerosis. I am writing to request that you reconsider your denial of the infusible disease modifying agent Tysabri (natalizumab) for this patient.

After his diagnosis the patient and I originally discussed and chose the medication Tecfidera to treat his multiple sclerosis, however he has continued to physically decline despite his commitment to his medication regimen, and his latest MRI on 7/17/15 demonstrated new inflammatory brain lesions.

Due to his continued issues, we feel a more aggressive medication is appropriate for this patient to help slow his disease progression, making the other medications

in your step therapy inappropriate choices. Tysabri has shown to be a very effective medication at both reducing the number of demyelinating lesions a patient presents with, but also slowing the side effects of that demyelination.

Due to the fact that this is an IV medication [Petitioner] has been enrolled in the TOUCH (Tysabri Outreach: Unified Commitment to Health) Prescribing Program, so that his response to medication as well as any side effects he may experience will be closely monitored at an approved Tysabri infusion site. He has also had his JC Virus drawn in preparation for starting Tysabri which was negative.

Director's Review

In its initial denial of coverage (a letter dated September 8, 2015) Priority Health stated: "If you try these two drugs and they do not work for you, Priority Health will cover your prescription for Tysabri." The Petitioner's doctor has explained why he believes Priority Health's required medications will not be effective for the Petitioner. In order to evaluate the question of the usefulness or medical necessity of the medications required by Priority Health, the Director presented that issue 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 board certified in neurology who has been in practice for more than 15 years and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and recommendation:

An MRI of the brain showed bilateral plaque formation when the member presented in August 2014. The member's complaints at that point were abnormalities in gait and fatigable weakness of the lower extremities. Despite treatment with Tecfidera, an MRI of the brain performed in December 2014 showed new lesions in the right parietal and frontal area in addition to clinically worsening gait. The member's neurologist has requested authorization to use Tysabri.

[O]f all the oral agents available, Tecfidera appears to have the greatest efficacy relative to reduction of clinical relapses and new lesion development... Tecfidera is superior to all other oral agents and interferons/Copaxone... [T]he only superior product is Tysabri... [I]n the setting of obvious aggressive disease, Tysabri is the best choice... [U]nder the circumstances present in this case, the requirement that the member must first try and fail 2 of 3 other drugs set specified in the Health Plan's policy is not medically appropriate.

Pursuant to the information set forth above and available documentation... Tysabri is medically necessary for treatment of the member's condition.

[Citations omitted.]

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, discerning no reason why the IRO’s recommendation should be rejected in the present case, finds that Tysabri is medically necessary to treat the Petitioner’s condition.

V. ORDER

The Director reverses Priority Health’s final adverse determination of September 24, 2015. Priority Health shall immediately provide coverage for Tysabri and shall, within seven days of providing coverage, furnish the Director with proof it implemented this order.

To enforce this order, the Petitioner may report any complaint regarding the implementation to the Department of Insurance and Financial Services, Health Care Appeals Sections, at this toll free telephone number: (877) 999-6442.

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