

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. 154386-001

Priority Health,

Respondent.

Issued and entered
this 8th day of August 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) asked her health plan, respondent Priority Health, to cover a brand name prescription drug. The request was denied.

On June 29, 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.* After a preliminary review of the material submitted, the Director accepted the request on July 7, 2016.

The Petitioner receives group health care benefits through Priority Health, 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 July 10, 2016.

The case involves medical issues so it was assigned to an independent review organization, which submitted its recommendation to the Director on July 27, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits, including prescription drugs, are defined in a certificate of coverage issued by Priority (the certificate).

The Petitioner has relapsing remitting multiple sclerosis (RRMS) and for over four years her condition was controlled through the use of the brand name prescription drug Copaxone 20 mg.

In October 2015 Priority changed its criteria for the use of Copaxone and the Petitioner began using Glatopa, a Copaxone generic. After she tried Glatopa for over three months her neurologist asked Priority to cover the continued use of Copaxone 20mg. Priority denied the request because the Petitioner did not meet its criteria.

The Petitioner appealed the denial through Priority's internal grievance process. At the conclusion of that process Priority issued a final adverse determination affirming its decision. The Petitioner now seeks a review of that final adverse determination by the Director.

III. ISSUE

Is Priority required to cover the prescription drug Copaxone 20 mg?

IV. ANALYSIS

Petitioner's Argument

In the request for an external review, the Petitioner wrote:

I would like my insurance company to cover Copaxone – they stopped allowing this medication to be covered. I was on this drug for MS for 4 years 9 months. They changed my treatment - have denied continually requests from my doctor to reinstate this necessary treatment.

In a letter to DIFS dated June 27, 2016, the Petitioner's physician's assistant explained:

[The Petitioner] is a patient of ours that we are seeing for her multiple sclerosis. She was diagnosed in 2010, and as you may be aware the first 5 years of this disease is indicative of the future prognosis of this disease. Although she did have some progression while on DAW¹ copaxone, it was minimal, and she tolerated it very well.

Her insurance appears to have changed its formulary and after multiple years of being on DAW copaxone and tolerating well, she was told she would have to switch to Gilenya, Tecfidera, Glatopa or Avonex.

¹ "Dispense as written," i.e., no generic substitutes.

She complied and was put on Glatopa. Unfortunately, she did not tolerate the inert ingredients in this formulation, causing significant site reactions that took weeks to resolve. She eventually had to discontinue this medication based on these effects.

We reviewed the alternative 'suggestions' by her insurance company. Given progression, we do not think a low dose interferon is appropriate for her. Given history of breast cancer, Gilenya was also not thought to be appropriate and since Tecfidera also causes potential leukopenia and possible PML we felt the best next option would be Rebif.

The Rebif is also not on the formulary, even though it is an older medication. She does tolerate this, though causes some site reactions and headache.

She is trying to maintain her working career and take care of her family, which is difficult enough when just dealing with MS alone. She is doing everything she can to remain a productive member of our community, and the difficulties she has had with getting the most appropriate medication approved is taking a large toll on her both mentally and physically (progression on MRI).

Given this, it is difficult to understand how the insurance company does not realize that the financial outcome for them is certainly greater when there is progression of disease, as compared to approving a medication that was working for her and allowing her to function at the best of her ability.

Priority Health's Argument

In its final adverse determination, Priority told the Petitioner:

Decision:

Uphold denial - requested coverage will not be provided as the Dispense as Written (DAW) exception criteria has not been met. Specifically, [the Petitioner] does not have a documented, immune-mediated allergy to a component used in Glatopa that is not found in brand name Copaxone, as outlined on the Priority Health Pharmacy Prior Authorization Form for Dispense as Written (DAW).

Director's Review

Priority denied coverage for Copaxone 20mg on the basis that the Petitioner did not meet its exception criteria for coverage. Those criteria are:

Patient must meet one of the following three criteria:

- Patient has a documented allergy to an inactive ingredient in the generic product.
- Patient is color blind and requires specific brand for identification purposes
- Patient has epilepsy and is currently stabilized on the brand name antiepileptic medication

Additional information

- Generic medications are subject to the same Food and Drug Administration (FDA) review process as the brand name equivalent counter part
- The FDA assures the approved generic medication is equivalent to the brand name counter part

The question of whether an exception should be made for Copaxone 20mg as medically necessary for the treatment of the Petitioner's condition was presented to an independent review organization (IRO) 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 Psychiatry & Neurology with a subspecialty in clinical neurophysiology; a member of the American Academy of Neurology and the American Epilepsy society; published in peer reviewed literature; and in active clinical practice. The IRO report included the following analysis and recommendation:

Reviewer's Decision and Principal Reasons for the Decision:

It is the determination of this reviewer that the brand-name prescription drug Copaxone is medically necessary for the treatment of the enrollee's condition.

Issue:

Evaluate the enrollee's request for the prescription drug Copaxone in light of the plan's drug formulary and MCL 3406o.

The enrollee requested brand-name Copaxone to be approved for the treatment of her multiple sclerosis. Copaxone has been a Food and Drug Administration (FDA) approved medication for the treatment of RRMS since 1996. The enrollee's insurance company requested that she try Glatopa, the generic form of Copaxone and after the enrollee complied, she developed significant injection site reactions. No other changes were made and from the description of the enrollee's clinical cutaneous

findings, it is quite clear that the enrollee had an allergic reaction to Glatopa. This would be consistent with the requirement of the insurance company to document an allergy to a component used in Glatopa and not brand-name Copaxone for the approval of brand-name Copaxone.

. . . The enrollee has a documented allergy to a non-active ingredient in the generic version (formulary) - Glatopa.

Clinical Rationale for the Decision:

The standard of care for a patient with the enrollee's clinical circumstances would require changing back to Copaxone 20 mg injections daily, which has been demonstrated to be better tolerated and resulting in fewer injection site reactions. Changing to a different multiple sclerosis (MS) disease modifying agent in order to accommodate the insurance plan formulary policy could put the enrollee at risk for an MS relapse, since the drugs listed in her formulary act through different mechanisms on the immune system to prevent MS exacerbations and they cannot be considered fully equivalent to Copaxone.

* * *

The enrollee has RRMS with relatively good control of her disease clinically and minimal progression on MRI while on Copaxone for five (5) years following her diagnosis. Glatiramer acetate is a complex drug made of a mixture of polypeptides which could have different immunogenicity when compared to a generic medication otherwise clinically equivalent such as Glatopa. Switching to Glatopa caused significant injection site reactions which were not present on brand-name Copaxone. The enrollee cannot tolerate Glatopa due to these site reactions, but she had a good response to the GA from brand name Copaxone. Clinically, it can be considered that the enrollee has an allergic reaction to Glatopa and not Copaxone. Therefore, for the reasons noted above, the brand-name prescription drug Copaxone is medically necessary for the treatment of the enrollee's condition.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Priority Health for the enrollee's request for the brand-name prescription drug Copaxone 20mg be overturned.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the 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 experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15). The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that Copaxone 20mg per day is medically necessary for the treatment of the Petitioner's condition and therefore Priority must make an exception and cover the drug for her.

V. ORDER

The Director reverses Priority Health's final adverse determination.

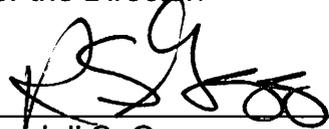
Priority Health shall immediately authorize prescription drug coverage for Copaxone 20mg DAW, and shall, within seven days of providing coverage, furnish the Director with proof it implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its 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 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