

**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. 153927-001

Health Alliance Plan of Michigan,

Respondent.

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Issued and entered  
this 21<sup>st</sup> day of July 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. BACKGROUND**

██████████ (Petitioner) was denied coverage for an injectable prescription drug by his health plan, respondent Health Alliance Plan of Michigan (HAP), a health maintenance organization.

On May 31, 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 prescription drug coverage from HAP. The Director immediately notified HAP of the external review request and asked for the information it used to make its final adverse determination. HAP responded on June 6, 2016. On June 7, 2016, after a preliminary review of the material submitted, the Director accepted the external review request.

Because the case involve a medical issue, it was assigned to an independent medical review organization which provided its recommendation to the Director on July 15, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are described in HAP's *HMO Group Subscriber Contract* (the contract).

The Petitioner has relapsing remitting multiple sclerosis. He has been treated with daily injections of Copaxone 20 mg since August of 2015 but is having injection site reactions. His neurologist recommended switching to Copaxone 40 mg three times per week and asked HAP to approve coverage. HAP denied the request because that dosage is not on its formulary.

The Petitioner appealed the denial through HAP's internal grievance process. At the conclusion of that process, HAP issued a final adverse determination dated April 1, 2016 affirming its denial. The Petitioner now seeks the Director's review of HAP's decision.

### III. ISSUE

Did HAP properly deny prescription drug coverage for Copaxone 40 mg?

### IV. ANALYSIS

#### Respondent's Argument

In its final adverse determination, HAP told the Petitioner:

On March 21, 2016, we received your Second Level Appeal requesting approval for the prescription drug Copaxone 40 mg.

**Final Internal Adverse Benefit Determination:** The Committee carefully considered all available evidence, previous decisions, your medication history, and the Information you presented during the hearing. The first and second level appeal letters submitted state that injection site reactions occur with Copaxone 20 mg. Injection site reactions occur, regardless of reducing the frequency of daily injections. Supportive measures are available to make self-injecting easier and less unpleasant such as: (1) optimizing the Injection technique; (2) select and rotate Injection site appropriately; (3) prior to injection the medication should be at room temperature; and (4) apply Ice to the injection site before and after to alleviate discomfort.

Other formulary options are available, with reduced administration time, such as Extavia given every other day and Rebif given three times weekly. In addition, Gilenya is the formulary preferred oral agent. The information submitted and presented does not indicate any contraindications for use of the formulary options. Since all formulary options have not been attempted and the medical records do not demonstrate failure to Copaxone 20 mg, with attempts to use the supportive measures as listed above, the criteria for a formulary exception are not met. Therefore, we uphold the original denial for the prescription drug Copaxone 40 mg.

### Petitioner's Argument

In an appeal letter to HAP dated March 14, 2016, the Petitioner said:

I am disappointed in your decision regarding my first level appeal to use Copaxone 40mg. While my doctor focused on injection site reactions to no avail in the first appeal, I am sending this letter to request a second level appeal revolving around two issues.

First: Copaxone 40mg is recognized as formulary by top-rated HMOs including the HMO an immediate family member uses for her 40mg Copaxone prescription.

Second: The alternatives on your formulary list listed in the rejection letter all have serious side effects which will inhibit my lifestyle as a mountaineer, climber, and backpacker.

Selected side effects from the drugs listed in your rejection letter:

- Avenex: Flu-like symptoms, heart problem, liver abnormalities
- Extavia: Flu-like symptoms, liver abnormalities
- Gilenya: Flu, diarrhea, back pain, liver issues
- Rebif: Flu-like symptoms, heart problems, liver abnormalities
- Tysabri: Fatigue, diarrhea

According to the National MS Society documents Copaxone does not cause these types of side effects.

Flu, flu-like symptoms, and fatigue can kill in the outdoors. These symptoms can cause a lack of concentration and general lessening of physical abilities which may contribute to falls, injuries, and death. In addition, heart and liver issues would also preclude me from having an active lifestyle.

\* \* \*

I am formally requesting HAP coverage and my personal use of Copaxone 40mg, a formulary medication for top-rated HMOs, to alleviate the injection site reactions while still allowing me to maintain my active lifestyle.

The Petitioner's neurologist wrote to HAP on January 7, 2016 to explain the request for Copaxone 40 mg:

[The Petitioner] was started on Copaxone 20 mg injections daily in August 2015 for his Multiple Sclerosis. He has not had any signs or symptoms of exacerbation since starting this medication. Other than injection site reactions he has been tolerating the medication. After daily injections he experiences redness, warmth, itching, and pain at the site that lasts up to 24 hours or more. It is be-

lieved by his injection specialist that that this could be due to low levels of body fat. Each injection site should be two inches apart. Due to his low levels of body fat [Petitioner] has to inject in the same spot fairly quickly. According to his injection specialist he has lost 50% of leg placements and 62% of arm placements.

Copaxone 40 mg is to be injected three times weekly as opposed to daily injections. The frequency of the 40 mg injections would benefit [the Petitioner] and reduce injection site reactions. I am asking that the denial of coverage of the 40 mg be reconsidered.

### Director's Review

HAP denied coverage for Copaxone 40 mg because it is not on its formulary, and there are other formulary drugs that the Petitioner has not tried. HAP has an exception process for non-formulary drugs which is described in HAP's "Commercial Formulary" (p. 3):

When your drug is not listed on the Formulary it is considered non-formulary. You or your doctor can ask us to make an exception and cover your drug and one of HAP clinical specialists will evaluate if the medication will be covered by your plan. However it is best to first discuss with your doctor or pharmacist if one of the formulary alternatives will work for you.

HAP declined to make an exception for the Petitioner.

To determine if an exception is appropriate in this case, the Petitioner's request and HAP's determination were 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 board certified in psychiatry and neurology with a subspecialty in clinical neurophysiology; a member of the American Academy of Neurology and the American Epilepsy Society; is published in peer reviewed literature; and is in active clinical practice. The IRO report included the following analysis and recommendation:

#### **Reviewer's Decision and Principal Reasons for the Decision:**

##### **Requested analysis:**

##### **Evaluate the enrollee's request in light of the plan's drug formulary.**

It is the determination of this reviewer that Copaxone 40 mg is medically necessary for the treatment of the enrollee's condition.

Copaxone 40 mg is considered medically necessary for the treatment of patients relapsing remitting multiple sclerosis. It was approved by the Food and Drug Administration (FDA) with this indication in January of 2014. The daily 20 mg subcutaneous injection was approved in 1996.

The enrollee's neurologist is requesting a change in medication from Copaxone 20 mg daily injections to Copaxone 40 mg three times per week for the treatment of relapsing remitting multiple sclerosis. This change is considered due to the presence of severe injection site reactions with the daily Copaxone use. According to the medical records, the enrollee had no MS relapses on Copaxone which confirms its efficacy in this case. Copaxone 40 mg is a non-formulary drug for this enrollee. However, the enrollee had a good response to Copaxone 20 mg in terms of MS control. Switching to a different MS disease modifying agent to accommodate the formulary request could result in worsening MS control in this case with a good documented response to Copaxone.

The enrollee is a thirty-six (36) year-old male with relapsing remitting MS. The enrollee has been free of new relapses since starting Copaxone 20 mg injections daily last year. However this has resulted in relatively severe injection site reactions. Typically, in similar cases the standard of care would require changing to Copaxone 40 mg injections three (3) [sic] which has been demonstrated to be better tolerated and resulting in fewer injection site reactions due to less frequent administration. Changing to a different 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 the formulary act through different mechanisms on the immune system to prevent MS exacerbations and they cannot be considered fully equivalent to Copaxone.

\* \* \*

Based on the documentation submitted, as well as the medical literature review, the Copaxone 40 mg is medically necessary for the enrollee.

**Recommendation:**

It is the recommendation of this reviewer that the denial issued by Health Alliance Plan of Michigan for Copaxone 40mg be overturned. [References 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 HAP's denial of prescription drug coverage for Copaxone 40 mg is not consistent with the terms of the Subscriber Contract or Michigan law.

**V. ORDER**

The Director reverses HAP's final adverse determination. HAP shall immediately coverage for Copaxone 40 mg for the Petitioner. MCL 550.1911(17). HAP shall, within seven days of providing coverage, furnish the Director with proof it has 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 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



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Randall S. Gregg  
Special Deputy Director