

**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. 150500-001**

**Molina Healthcare of Michigan, Inc.,**  
**Respondent.**

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Issued and entered  
this 24<sup>th</sup> day of November 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

██████████ (Petitioner) was denied coverage for a prescription drug by his health plan, respondent Molina Healthcare of Michigan (Molina).

On October 22, 2015, he 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. On October 29, 2015, after a preliminary review of the material submitted, the Director accepted the request.

The Petitioner is enrolled in the Healthy Michigan Plan, a low-income health care program of the Michigan Department of Health and Human Services. The plan's benefits are administered by Molina, a Medicaid health maintenance organization. The Director immediately notified Molina of the external review request and asked for the information it used to make its final adverse determination. Molina provided its response on October 28, 2015.

To address the medical issues in the case, the Director assigned it to an independent medical review organization, which provided its analysis and recommendation on November 12, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner's prescription drug benefits are defined in Molina's *Healthy Michigan Plan Welcome Kit Member Handbook* (the handbook). The handbook includes a certificate of coverage (the

certificate). The Petitioner's coverage with Molina was effective September 1, 2015.

The Petitioner has a presumptive diagnosis of multiple sclerosis (MS). It is not certain if he has primary progressive MS (PPMS), for which there is no approved treatment, or relapsing remitting MS (RRMS). His physician asked Molina to authorize coverage for the drug Copaxone, used to treat RRMS.<sup>1</sup> Molina denied the request on the basis that the Petitioner did not meet its criteria for coverage.

The Petitioner appealed the denial through Molina's internal grievance process. At the conclusion of that process, Molina affirmed its denial in a final adverse determination dated October 20, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

### III. ISSUE

Is Molina required to cover the prescription drug Copaxone?

### IV. ANALYSIS

#### Molina's Argument

In its final adverse determination, Molina explained to the Petitioner the reasons for its denial:

. . . The Appeal Review Committee . . . made the decision to deny your request for Copaxone for Multiple Sclerosis.

#### Reasons for the Denial

The original request was denied because the medication does not meet Molina Healthcare MCG-149 (Medical Coverage Guidance) Criteria. Per the criteria progress notes dated within the last 6 months documenting the member's diagnosis, treatment plan, and response to previous medications along with a current MRI are required prior to approval and was not received.

The documentation (clinical or office notes) that Molina received from your provider, after the original denial, shows that you have a diagnosis of Primary Progressive Multiple Sclerosis (PPMS). Per Molina Healthcare MCG-149 a diagnosis of Relapsing Remitting Multiple Sclerosis (RRMS) is required prior to approval. Copaxone is not FDA approved for the treatment of PPMS.

In your appeal conference, a suggestion was made for you to get a second opinion, to confirm your diagnosis, by a different neurologist.

Your request was denied based on the Molina Healthcare MCG-149 (Medical Coverage Guidance) Criteria.

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<sup>1</sup> Copaxone is included on the Healthy Michigan Plan's *Preferred Drug List* as both a "preferred" and "non-preferred" agent for multiple sclerosis.

When the Petitioner enrolled with Molina, the plan approved a one-month prescription of Copaxone as part of his transition from his prior health plan. However, Molina declined to extend that prescription because it believes that the Petitioner did not meet its criteria for continued coverage.

### Petitioner's Argument

The Petitioner's neurologist explained, in an August 21, 2015, letter, why he wanted to treat him with Copaxone:

The patient was seen today for neurological follow-up visit. The patient is still feeling terrible with shortness of breath, tremor, numbness, fatigue, dizziness. The exam showed him to be in no acute distress. No objective neurological deficit. Gait is steady on narrow base. Did tandem without difficulties. The spinal fluid was clear and colorless with zero cells, normal protein and glucose, however, oligoclonal bands were positive with 11 unique bands in the CSF, not present in the serum. The IgG index was borderline high. ACE negative. B12 and sed rate normal.

I explained the results of the test to him. . . . W[hen] the findings are combined with the MRI results and his family history it seems we are dealing with a case of multiple sclerosis, but potentially it is of the progressive rather than relapsing, remitting type. It seems that this sister has progressive MS, while his cousin has a suspected and not confirmed yet case of MS. There are also other autoimmune diseases in the family including another sister with SLE and the patient has Crohn's disease. I told him that there is no approved treatment for primary progressive multiple sclerosis; however, since we are not sure I will treat him with Copaxone. I do not think he is a candidate for any of the oral agents because of the presence of HIV knowing that those agents are immune suppressants and will make him prone to opportunistic infection more. . . .

### Director's Review

The Petitioner's plan covers prescription drugs. Injectable Copaxone is one of the drugs that requires prior approval. Molina declined to approve Copaxone because it said the Petitioner did not meet the criteria of its medical policy; i.e., it was not medically necessary.

To resolve the medical issue in this case, the Director assigned it to an independent review organization (IRO) for analysis and a recommendation 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; is published in peer reviewed literature; and is in active clinical practice. The IRO reviewer explained that while the Petitioner does not meet Molina's criteria for coverage, Copaxone is nevertheless medically necessary to treat his condition:

**Clinical Rationale for the Decision:**

The standard of care for a patient with a clinical scenario as this enrollee's condition includes starting a disease modifying agent, such as injectable Copaxone, interferons (Rebif and Avonex) or one of the oral drugs (Tecfidera and Gilenya).

\* \* \*

The enrollee's brain MRI shows white matter lesions bilaterally and the CSF is abnormal, with evidence of oligoclonal bands and elevated IgG index. This is suggestive for a demyelinating disorder. The main differential diagnosis in this case, once other autoimmune disorders have been ruled out, is between PPMS and RRMS. In a letter dated August 21, 2015, the enrollee's neurologist did consider a potential case of PPMS in the differential diagnosis, but this diagnosis is only considered as an alternative possibility to RRMS and is not certain. RRMS remains a strong diagnostic consideration. PPMS is a very uncommon disorder with a severe progressive course and very few treatment options are found to be effective at this time. RRMS is far more frequent and has multiple treatment options available. Quite frequently, a prolonged period of observation over several months may be needed to definitely diagnose RRMS vs PPMS.

Copaxone is approved by the FDA for treatment of RRMS. This is by far the most common form of MS and given the MRI/CSF and clinical symptoms, it should be considered the most likely diagnosis for this enrollee until proven otherwise by a different clinical course. Therefore, the Copaxone is medically necessary for this enrollee.

Molina's criteria of coverage specify the use of Copaxone only for clinically definite RRMS. Since there is not a clinically definite diagnosis of RRMS, the prescription drug Copaxone does not meet the health plan's criteria. But, based on the documentation submitted for review, there is still some debate whether this could be a PPMS versus RRMS, but very often this distinction can be only made by observing the patient for a longer period of time during which treatment is needed.

For the reasons noted above, the prescription drug Copaxone does not meet the health plan's criteria, but 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 Molina Healthcare of Michigan, Inc. for the prescription drug Copaxone 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 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 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, finds that injectable Copaxone, a covered drug, is a medically necessary to treat the Petitioner's condition and therefore is a covered benefit under the Petitioner's health plan.

#### V. ORDER

The Director reverses Molina's final adverse determination of October 20, 2015. Molina shall immediately authorize and provide prescription drug coverage for Copaxone, and shall within seven days of approving coverage, furnish the Director with proof it has 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 Section, 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:



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Randall S. Gregg  
Special Deputy Director