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. 148035-001**

Molina Healthcare of Michigan, Inc.,

Respondent.

Issued and entered
this 9th day of July 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On May 26, 2015, (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 health care benefits from Molina Healthcare of Michigan (Molina), a health maintenance organization for Medicaid-eligible individuals. The Director notified Molina of the external review request and asked for the information it used to make its final adverse determination. The Director received Molina's response on May 28, 2015. After a preliminary review of the material submitted, the Director accepted the request on June 2, 2015.

Because medical issues are involved, the Director assigned the matter to an independent review organization which provided its analysis and recommendation on June 17, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in a certificate of coverage issued by Molina (the certificate) and include prescription drugs.

After experiencing symptoms such as bilateral ocular pain, upper extremity pain, diffuse muscle spasms, and headaches, the Petitioner was diagnosed with "an immune mediated autonomic neuropathy with albumin-cytological dissociation." When her physician recommended a six-month trial of the intravenous immunoglobulin (IVIG) Gammagard S-D, a drug used to treat primary immunodeficiency, Molina denied coverage.

The Petitioner appealed the denial through Molina's internal grievance process. At the conclusion of that process, Molina issued a final adverse determination dated May 8, 2015, upholding its denial. The Petitioner now seeks a review of that final adverse determination from the Director.

III. Issue

Did Molina correctly deny authorization and coverage for Gammagard S-D?

IV. Analysis

Molina's Argument

In its final adverse determination, Molina wrote:

> . . . The [Appeal Review] Committee made the decision to deny your request for Gammagard S-D 5GM Vial for treatment.
>
> Reason for the Denial
>
> Molina Healthcare has reviewed the request for Gammagard S-D 5GM and determined that it is not a covered benefit. Per the Michigan Department of Community Health Medicaid Provider Manual, Pharmacy Section 6: Non-Covered Services, experimental medications or investigational medications are not a covered benefit.

Petitioner's Argument

On the request for external review form the Petitioner said:

> After several appeals from my Dr. . . . and an appeal from myself, Molina is still denying my treatment of [intravenous immunoglobulin] for my diagnosis. Molina hasn't given us a proper explanation as to why I shouldn't be allowed to proceed with treatment as my doctor requests. IVIG is my only hope.

The Petitioner's neurologist explained the reason for the Gammagard S-D in a letter dated March 3, 2014:

> . . . [The Petitioner] is a 37-year-old woman who developed symptoms of waxing and waning autonomic dysfunction. She underwent a diagnostic evaluation that included a CSF examination that demonstrated albuminocytologlcal dissociation with a protein of 73 mg/dL. This confirmed my diagnosis of an immune mediated idiopathic autonomic neuropathy. Her condition is well described in the academic Neurology literature including the text that I edited.
>
> Moreover, the medical literature is very clear that immunomodulation therapy with intravenous immune globulin is the first line treatment for this condition. In fact it is the next logical step. Therefore, my request for a one year course of IvIg is logical and medically sound.

> It is my understanding that this treatment was denied because it is not considered a covered benefit by her policy. However, this condition is so rare that it was probably not even considered for inclusion in the policy in the first instance. This is why I am strongly recommending that you approve this treatment on appeal.

Director's Review

It is Molina's position that the IVIG Gammagard S-D is not a benefit because it is experimental or investigational for treating the Petitioner's condition. Molina cites a provision in the Medicaid Provider Manual[1] that says:

> The following drug categories are **not covered** as a benefit:
>
> * * *
>
> - Experimental or investigational drugs

The certificate also has this exclusion in "Appendix C – Excluded Services & Limitations" (pp. 25, 26):

> Any services, equipment or supplies excluded or limited under the Medicaid Contract are excluded or limited under the Member Agreement, even when recommended by a Primary Care Provider or Participating Provider and/or written on a Plan referral form. Exclusions and limitations include, but are not limited to, the following:
>
> * * *
>
> 14. **Experimental, Investigational or Research Drugs, Biological Agents, Devices, Supplies, Treatments, Procedures or Equipment**. These services are not covered.

The question of whether IVIG Gammagard S-D is experimental or investigational for the treatment of the Petitioner's condition was presented 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 and Neurology with a subspecialty in clinical neurophysiology and is in active practice. The IRO report included the following:

> **Reviewer's Decision and Principal Reasons for the Decision:**
>
> It is the determination of this reviewer that the enrollee does not meet criteria for coverage of the prescription drug Gammagard S-D 5mg vial and therefore the prescription drug is not medically necessary for the treatment of the enrollee's condition.

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1 April 1, 2015, version; pharmacy chapter, "Section 6 – General Noncovered Services," p. 12.

Clinical Rationale for the Decision:

Autoimmune autonomic dysfunction with acute onset is a relatively rare disorder. It usually presents with significant orthostatic dizziness and syncopal or presyncopal episodes which are not mentioned in this enrollee's history. The enrollee's diagnosis, according to her clinical notes, remains unclear. If her autonomic testing is abnormal and she is positively diagnosed with an autoimmune autonomic neuropathy, then IVIG could be a treatment consideration although the evidence is based mainly on case reports, since this is a rare disorder and no large-scale trials are available. Otherwise, the treatment remains symptomatic.

Yoshimaru K et al describes a case of acute idiopathic autonomic neuropathy (AIAN) in which intravenous administration of IVIG proved effective. A thirty two (32) year old male was admitted with orthostatic dizziness. Fever and headache first developed twenty four (24) days earlier and persisted for ten (10) days, when orthostatic dizziness developed and prevented him from walking. Hypohidrosis, constipation and impotence also developed. Neurological examinations revealed no abnormalities. Cerebrospinal fluid showed an increase level of protein (70 milligrams/deciliter [mg/dl]). A head-up tilt test revealed that blood pressure decreased from 120/60 millimeter of mercury (mmHg) when supine to 60/40 mmHg in a head-up position and the patient complained of dizziness. Dizziness disappeared after initiating IVIG (0.4 grams/kilograms [g/kg]). A head-up tilt test was performed seven (7) days after IVIG, revealing blood pressures of 106/61 mmHg when supine and 103/71 mmHg in a head-up position. These results suggest that IVIG should be considered as a choice to treat early AIAN.

Ureda A. and authors report a case of acute autonomic, sensory and motor neuropathy (AASMN) with severe orthostatic hypotension. Although the effectiveness of corticosteroid was insufficient, high dose IVIG was effective for not only sensorimotor symptoms but also autonomic symptoms. This is the first case of AASMN showing favorable responses to IVIG treatment, suggesting that IVIG should be considered when corticosteroid therapy or plasmapheresis is ineffective or insufficient.

As noted, in both articles, the orthostatic hypotension associated with generalized autonomic dysfunction was one of the most salient features of the case. This was particularly absent in this enrollee' case. At this point, the cause of this enrollee's symptoms remains unclear. There is no evidence of abnormal autonomic testing confirming the presence of an autonomic dysfunction in this enrollee. The increase in her CSF protein level is moderate and clearly abnormal but nonspecific. It is not clear whether this abnormal finding is responsible for the enrollee's symptoms therefore the prescription drug is not medically necessary for the treatment of the enrollee's condition.

The cause of this enrollee's symptoms remains unclear. There is no evidence of abnormal autonomic testing confirming the presence of an autonomic dysfunction in this enrollee. In this clinical scenario with an unclear diagnosis, the treatment with Gammagard would be considered experimental.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Molina Healthcare of Michigan, Inc. for the prescription drug Gammagard S-D 5mg vial be upheld. [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 recommendation is afforded deference by the Director. In a decision to uphold or reverse a final 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 certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected, finds that IVIG therapy is experimental for use in the Petitioner's case and thus not medically necessary to treat her condition.

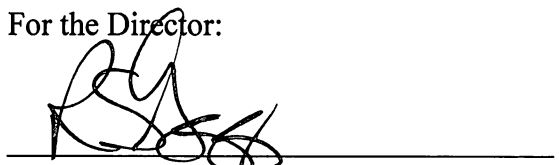
V. ORDER

The Director upholds Molina's May 8, 2015, final adverse determination.

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