[redacted]

Date Mailed: December 22, 2022
MOAHR Docket No.: 22-004981
Agency No.: 40344118
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Steven Kibit

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and upon the Petitioner's request for a hearing.

After due notice, a telephone hearing was held on December 8, 2022. Petitioner appeared and testified on her own behalf. Adam Herrmann, Clinical Pharmacist, appeared and testified on behalf of Meridian Health Plan, the Respondent Medicaid Health Plan (MHP).

During the hearing, Respondent submitted an evidence packet that was admitted into the record as Exhibit A, pages 1-67. Petitioner did not submit any exhibits.

ISSUE

Did Respondent properly deny Petitioner's request for Aimovig Soln Auto-inj 140 MG/ML?

FINDINGS OF FACT

The Administrative Law Judge, based upon the competent, material, and substantial evidence on the whole record, finds as material fact:

1. Petitioner is a thirty-four (34) year-old Medicaid beneficiary who is enrolled in the Respondent MHP. (Exhibit A, page 7).

2. On September 22, 2022, Respondent received a prior authorization request for Aimovig Soln Auto-inj 140 MG/ML submitted on Petitioner's behalf by her doctor. (Exhibit A, pages 7-9).

3. In part, the request indicated that Petitioner has been diagnosed with chronic migraines. (Exhibit A, page 7).

4. It also indicated that the Aimovig was to be used together with Botox to treat Petitioner's migraines. (Exhibit A, page 8).

5. Treatment of migraines through a combination of Aimovig and Botox has not been approved by the United States Food and Drug Administration (FDA). (Testimony of Clinical Pharmacist).

6. Respondent sent Petitioner written notice that the prior authorization request had been denied. (Exhibit A, pages 12-19).

7. With respect to the reason for the denial, the notice stated:

> **This action is based on the following:**
>
> A pharmacist has reviewed all documentation submitted with this request for AIMOVIG Soln Auto-inj and determined that it does not meet the coverage criteria. The request for this drug is denied. The request is denied because it did not meet the following criteria : Use of AIMOVIG Soln Auto-inj 140MG/ML and BOTOX together for CHRONIC MIGRAINE WITHOUT AURA, INTRACTABLE, WITHOUT STATUS MIGRAINOSUS is supported by evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines, and you have tried at least two preferred drugs that are commonly used to treat your condition at the highest possible dose, or you had a bad reaction, or all cannot be used. The documentation provided for review does not show that you have met the criteria for approval at this time. The plan will cover (Metoprolol Tartrate Tab 100 MG) and others within quantity limits, without prior authorization. Please discuss your plan of care with your physician.
>
> Source of criteria: CP.PMN.53, Off-Label Use

Exhibit A, page 12

8. On October 4, 2022, Petitioner filed an Internal Appeal with Respondent regarding that decision. (Exhibit A, pages 20-46).

9. As part of that Internal Appeal, Petitioner included a letter from her medical provider in which the provider wrote in part:

> This letter is in regard to a denial received for the coverage of Aimovig for the above-named patient. This is a medically necessary treatment for this patient, and the denial of medical treatment for this patient has the potential to cause long-term significant harm to the patient's physical and mental health. For this patient, the combination of Botox and Aimovig has proven superior to utilizing one or the other by itself. Previously, when the patient was on Botox treatment alone, she was experiencing severe migraine of pain level 7+/10 approximately 1-2 days per week, with a daily average pain level of 6/10. She was missing a significant amount of family and social activities, being completely debilitated about 2 days per week and the rest of the week only being able to function for about 5 hours of the day.
>
> When she was on the combination of Botox and Aimovig, she was able to achieve significant improvement in her migraine headaches. She only had approximately 2 days per month with severe migraine pain of 7/10 or higher, with most of the days of the month at a pain level of 2-3/10 and an average pain level of 3/10.
>
> In the past when patient was on monotherapy, she experienced significant worsening in migraine and a drastic decrease in her ability to function due to spending a large amount of time in severe pain, and her mood worsened considerably, as evidenced by her high PHQ-9 scores and having thoughts of self-harm more than half the days of the month.
>
> The patient has already tried numerous other preventative medications including Amitriptyline, Cymbalta, Topamax, Lisinopril, magnesium, and riboflavin. Propranolol and other beta-blockers are not advisable due to the patient's history of asthma and severe

> depression.
>
> In order to provide the most effective treatment and the highest quality of life for the patient, it is medically necessary for the patient to be on the combination of Botox and Aimovig. **Failure to approve this combination of therapy will lead to detrimental long-term consequences for this patient, resulting in a severe decrease in physical and mental health.**

Exhibit A, pages 31-32

10. On October 17, 2022, Respondent sent Petitioner written notice that her Internal Appeal was denied. (Exhibit A, pages 47-57).

11. With respect to the reason for the denial, the notice stated:

> A pharmacist and a physician have reviewed all documentation submitted with this appeal request for AIMOVIG Soln Auto-inj and determined that it does not meet the coverage criteria. The request for this drug is denied. The request is denied because it did not meet the following criteria : Use of AIMOVIG Soln Auto-inj 140MG/ML and BOTOX together for CHRONIC MIGRAINE WITHOUT AURA, INTRACTABLE, WITHOUT STATUS MIGRAINOSUS is supported by evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines, and you have tried at least two preferred drugs that are commonly used to treat your condition at the highest possible dose, or you had a bad reaction, or all cannot be used. The documentation provided for review does not show that you have met the criteria for approval at this time. The plan will cover (Metoprolol Tartrate Tab 100 MG) and others within quantity limits, without prior authorization. Please discuss your plan of care with your physician.

Exhibit A, page 49

12. On November 2, 2022, the Michigan Office of Administrative Hearings and Rules (MOAHR) received the request for hearing filed by Petitioner in this matter regarding Respondent's decision. (Exhibit A, pages 1-4).

CONCLUSIONS OF LAW

The Medical Assistance Program is established pursuant to Title XIX of the Social Security Act and is implemented by Title 42 of the Code of Federal Regulations (CFR). It is administered in accordance with state statute, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

In 1997, the Department received approval from the Health Care Financing Administration, U.S. Department of Health and Human Services, allowing Michigan to restrict Medicaid beneficiaries' choice to obtain medical services only from specified Medicaid Health Plans.

The Respondent is one of those MHPs and, as provided in the Medicaid Provider Manual (MPM), is responsible for providing covered services pursuant to its contract with the Department:

> The Michigan Department of Health and Human Services (MDHHS) contracts with Medicaid Health Plans (MHPs), selected through a competitive bid process, to provide services to Medicaid beneficiaries. The selection process is described in a Request for Proposal (RFP) released by the Office of Purchasing, Michigan Department of Technology, Management & Budget. The MHP contract, referred to in this chapter as the Contract, specifies the beneficiaries to be served, scope of the benefits, and contract provisions with which the MHP must comply. Nothing in this chapter should be construed as requiring MHPs to cover services that are not included in the Contract. A copy of the MHP contract is available on the MDHHS website. (Refer to the Directory Appendix for website information.)
>
> MHPs must operate consistently with all applicable published Medicaid coverage and limitation policies. (Refer to the General Information for Providers and the Beneficiary Eligibility chapters of this manual for additional information.) Although MHPs must provide the full range of covered services listed below, MHPs may also choose to provide services over and above those specified. MHPs are allowed to develop prior authorization requirements and utilization management and review criteria that differ from Medicaid requirements. The following subsections describe covered

> services, excluded services, and prohibited services as set forth in the Contract.
>
> *MPM, July 1, 2022 version*
> *Medicaid Health Plan Chapter, page 1*
> *(underline added for emphasis)*

As allowed by the above policy and its contract with the Department, the MHP has developed prior authorization requirements and utilization management and review criteria; and has limited coverage to those consistent with all the Department's applicable published Medicaid coverage and limitation policies. In part, that policy provides:

> **8.3 NONCOVERED SERVICES**
>
> The items or services listed below are not covered by the Medicaid program:
>
> - Acupuncture
> - Autopsy
> - Biofeedback
> - All services or supplies that are not medically necessary
> - Experimental/investigational drugs, biological agents, procedures, devices, or equipment
> - Routine screening or testing, except as specified for EPSDT or by Medicaid policy
>
> *MPM, July 1, 2022 version*
> *General Information for Providers Chapter, page 23*
> *(underline added for emphasis)*

Additionally, regarding off-label use, Respondent's review criteria also provides:

> **Description**
> Off-label drug use is the utilization of an FDA-approved drug for uses other than those listed in the FDA-approved labeling or in treatment regimens or populations that are not included in approved labeling.

FDA Approved Indication(s)
Varies by drug product.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that all medical necessity determinations for off-label uses be considered on a case-by-case basis by a physician, pharmacist, or ad hoc committee, using the guidance provided within this policy.

* * *

B. Requests for Off-label Use through Medical Benefit (must meet all):

1. There are no pharmacy and therapeutic committee approved off-label use criteria for the diagnosis;
2. Use is supported by one of the following (a, b, or c):
   a. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B (see Appendix D);
   b. Evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (i – iv):
      i. Adequate representation of the member's clinical characteristics, age, and diagnosis;
      ii. Adequate representation of the prescribed drug regimen;
      iii. Clinically meaningful outcomes as a result of the drug therapy in question;
      iv. Appropriate experimental design and method to address research questions (see Appendix F for additional information);
   c. Micromedex DrugDex® with strength of recommendation Class I or IIa (see Appendix D);
3. Treatment is not for a benefit-excluded use (e.g., cosmetic);
4. Prescribed by or in consultation with an appropriate specialist for the diagnosis;
5. Failure of an adequate trial of at least two FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist, at

maximum indicated doses, unless clinically significant adverse effects are experienced, all are contraindicated, or request is for a product for treatment associated with cancer for a State with regulations against step therapy in certainoncology settings (see Appendix E);

6. Failure of an adequate trial of, or clinically significant adverse effects to, two generics* (each from a different manufacturer) or the preferred biosimilar(s) of the requested brand name drug, if available, unless one of the following is met (a or b):
   a. Member has contraindications to the excipients in all generics/biosimilars;
   b. Request is for a product for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (see Appendix E); *If a second generic of the requested brand name drug is not available, member must try an alternative that is FDA-approved or supported by standard pharmacopeias (e.g., DrugDex) for the requested indication, provided that such agent exists
7. Member has no contraindications to the prescribed agent per the product information label;
8. If applicable, prescriber has taken necessary measures to minimize any risk associated with a boxed warning in the product information label;
9. Dosing regimen and duration are within dosing guidelines recommended by clinical practice guidelines and/or medical literature. Approval duration: Duration of request or 6 months (whichever is less)

Exhibit A, pages 61-61

Here, Respondent denied the prior authorization request at issue in this case pursuant to the above policies and on the basis that the requested procedure is experimental.

Specifically, Respondent's Clinical Pharmacist testified that, as the requested use of Aimovig in combination with Botox to treat migraine headaches is not approved by the FDA, Respondent consequently reviewed the request under its Off Label Use policy; Respondent did not find any supportive evidence, such as medical studies or clinical practice guidelines, for the requested use; Petitioner's medical provider did not identify any such support either; and the request therefore had to be denied as experimental.

In response, Petitioner agreed that requested use of Aimovig in combination with Botox to treat migraine headaches is not approved by the FDA and that there is no medical literature or studies supporting her claim either. However, Petitioner also testified the treatment is actually working for her and that it is the only thing that has worked for her

over years and years of treatment. She further testified that Aimovig with Botox is the only way she can have a normal life. Petitioner also testified that the next option raised by her doctor is opioids, but that neither Petitioner nor her doctor want to pursue that option as it is not in Petitioner's best interest.

Petitioner has the burden of proving by a preponderance of the evidence that the MHP erred in denying her authorization request. Moreover, the undersigned Administrative Law Judge is limited to reviewing Respondent's decision in light of the information that was available at the time the decision was made.

Given the above policies and evidence in this case, Petitioner has failed to meet her burden of proof and Respondent's decision must therefore be affirmed. Medicaid does not cover experimental drugs and it is undisputed in this case both that the medication at issue has not been approved by the FDA for the treatment sought by Petitioner and that the medication does not meet Respondent's Off Label Use policy given the absence of any studies, trials or guidelines supporting the requested treatment. Moreover, while Petitioner has tried the treatment in the past, with both Petitioner's credible testimony and the letter from her doctor describing successful results, that past usage is insufficient on its own to demonstrate that the requested medication is not experimental or that Respondent erred.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that Respondent properly denied Petitioner's prior authorization request.

IT IS, THEREFORE, ORDERED that:

Respondent's decision is **AFFIRMED.**

SK/sj

Steven Kibit
Administrative Law Judge

NOTICE OF APPEAL:

Petitioner may appeal this Order in circuit court within 30 days of the receipt date. A copy of the circuit court appeal must be filed with the Michigan Office of Administrative Hearings and Rules (MOAHR).

A party may request a rehearing or reconsideration of this Order if the request is received by MOAHR within 30 days of the date the Order was issued. The party requesting a rehearing or reconsideration must provide the specific reasons for the request. MOAHR will not review any response to a request for rehearing/reconsideration.

A written request may be mailed or faxed to MOAHR. If submitted by fax, the written request must be faxed to (517) 763-0155; Attention: MOAHR Rehearing/Reconsideration Request.

If submitted by mail, the written request must be addressed as follows:

Michigan Office of Administrative Hearings and Rules
Reconsideration/Rehearing Request
P.O. Box 30763
Lansing, Michigan 48909-8139

Via Electronic Mail:

DHHS Department Contact
Managed Health Care Division
CCC, 7th Floor
Lansing, MI 48919
MDHHS-MCPD@michigan.gov

Community Health Representative
Katie Feher
Meridian Health Plan of Michigan Inc.
1 Campus Martius, Suite 700
Detroit, MI 48226
Katie.feher@CENTENE.com

Via First Class Mail:

Respondent Representative
Adam Herrmann
Meridian Health Plan of Michigan Inc.
1 Campus Martius, Suite 700
Detroit, MI 48226

Petitioner
[redacted]