[redacted], MI [redacted]

Date Mailed: May 19, 2020
MOAHR Docket No.: 20-002223
Agency No.: [redacted]
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Robert J. Meade

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9, 42 CFR 431.200 *et seq*. and 42 CFR 438.400 *et seq*. upon Petitioner's request for a hearing.

After due notice, a hearing was held on May 13, 2020. Dr. [redacted] appeared and testified on behalf of Petitioner, [redacted]. [redacted], Nurse, appeared as a witness for Petitioner. Elizabeth Wysocki, Senior Manager Appeals, appeared on behalf of Meridian Health, the Respondent Medicaid Health Plan (Meridian or MHP). Dr. Adam Herrman, RpH, appeared as a witness for the MHP.

ISSUE

Did the MHP properly deny Petitioner's prior authorization request for the medication Xolair?

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 [redacted]-year-old Medicaid beneficiary, born [redacted], who has been diagnosed with severe persistent asthma and who is enrolled in the Respondent MHP. (Exhibit A, p 13; Testimony)

2. On February 28, 2020, the MHP received a prior authorization request from Petitioner's provider for the medication Xolair. (Exhibit A, pp 12-13; Testimony)

3. On March 11, 2020, the MHP sent Petitioner and her provider written notice that the prior authorization request was denied because the records submitted did not meet the coverage criteria. Specifically, the notice indicated that the records submitted did not show clinical

documentation of severe persistent asthma for greater than 1 year, FEV1 greater than 40% to less than 80%, evidence of daily use of rescue inhalers, documentation of trial and failure of oral corticosteroids, documentation of hospitalizations or ER visits for uncontrolled allergic asthma, positive skin allergy testing/RAST, documentation of IgE levels between 30-700 IU/ml, and documentation of trial and failure of combination therapies for at least 6 months. (Exhibit A, pp 15-23; Testimony)

4. On March 20, 2020, Petitioner filed an Internal Appeal and submitted additional documentation. (Exhibit A, pp 24-46; Testimony)

5. On March 23, 2020, the MHP sent Petitioner a Notice of Internal Appeal Decision, which upheld the denial of Petitioner's prior authorization request. (Exhibit A, pp 48-55; Testimony)

6. On March 30, 2020, the Michigan Office of Administrative Hearings and Rules (MOAHR) received Petitioner's request for hearing. (Exhibit A, pp 1-8)

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 statutes, 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.
>
> *Medicaid Provider Manual*
> *Medicaid Health Plan Chapter*
> *January 1, 2020, p 1*
> *(Emphasis added)*

Similarly, the MHP's contract with the Department provides:

> The Contractor may have a prescription drug management program that includes a drug formulary. DCH may review the Contractor's formularies regularly, particularly if enrollee complaints regarding access of care have been filed regarding the formulary. The Contractor must have a process to approve physicians' requests to prescribe any medically appropriate drug that is covered under the Medicaid Pharmaceutical Product List (MPPL).

Pursuant to the above policy and its contract with the Department, the MHP has developed a drug management program that includes a drug formulary and provides that its covered services are subject to the limitations and restrictions described in the MHP's Medicaid agreement, the MPM, Medicaid bulletins, and other directives.

With regard to Xolair, the Medicaid Health Plan Criteria provide, in relevant part:

> **VI. Criteria for Use:**
>
> a. Asthma
>
> A. Clinically documented severe persistent asthma for greater than 1 year; reversible airflow obstruction, bronchial hyperactivity (challenged), FEV1 > 40% to < 80% of predicted normal pre-inhaled steroids, PEV variability > 30%
>
> B. Daily use of short acting beta-agonist (SABA)

C. Hospitalizations and ER visits for uncontrolled allergic asthma

D. Ruled out co-morbidities that can cause asthma exacerbation; sinusitis, GERD, allergic rhinitis, OTC and Rx medications

E. Rule out non-asthma diagnosis; hyperventilation, laryngeal dysfunction, panic disorder

F. Clinically documented IgE levels between 30 – 700 IU/ml

G. Clinically documented specific allergic sensitivity; positive skin testing or RAST, in vitro testing to at least one perennial aeroallergen (dust mites, mold, animal dander, cockroaches, etc)

H. Failed/intolerant to oral corticosteroids (at least 2 courses within the past 12 months for asthmatic exacerbations or the inability to wean from systemic corticosteroids)

I. Failed/intolerant to combination therapies; high dose inhaled steroids (ICS), long acting beta-agonists (LABA), antileukotrienes, theophylline, for at least 6 months

J. Ages 6 and older

K. Body weight less than or equal to 150 kg (330 lbs)

L. Must have a consult by pulmonary specialist or allergist

M. Current clinical documents must be submitted

N. Serum cotinine as evidence of not smoking

O. Clean Drug Screening

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VII. Required Medical Information:

a. Proper diagnosis of an FDA approved indication

b. Negative drug screening

c. Documentation of dose, dates of therapy and clinical outcomes of therapies previously tried and failed

d. Chart notes of compliance

e. Documentation of Pulmonary Function tests (FEV, PFT) when the indication for use is asthma

f. Drug screening every 3 monthsSerum cotinine testing every 3 months with asthma diagnosis

(Exhibit A, pp 56-66, Emphasis added)

In this case, the denial of the prior authorization request was based on the fact that the requested medication, Xolair is only approved with documentation that the member has had a trial and failure of combination therapies for at least 6 months and the documentation submitted by Petitioner here fell short of that criteria. Respondent's witness explained that Xolair is an add-on medication usually prescribed after base medications are unsuccessful. Here, Respondent's witness indicated that Petitioner's claims history for the base medications was spotty and she missed approximately 50% of the refills for those medications in the six months leading up to the request.

Petitioner's doctor testified that he has been seeing Petitioner for asthma since she has been about two year old. Petitioner's doctor indicated that in that time frame, Petitioner has had a difficult history with at least six emergency department visits and two hospital admissions. Petitioner's doctor reviewed Petitioner's medical history and indicated that Petitioner was started on an inhaler at about five years old but had several exacerbations thereafter. Petitioner's doctor indicated that at age seven, Petitioner was started on Singular, plus another inhaler and three months later she had to be admitted to the hospital. Petitioner's doctor testified that he then tried Petitioner on a low dose of Symbicort, because of her age, but increased the dosage following a previous appeal with the health plan.

Petitioner's doctor testified that Petitioner had another exacerbation in September 2019 after switching to the higher dose of Symbicort, so he decided to start Petitioner on Xolair because he had samples of the medication. Petitioner's doctor testified that Petitioner was able to remain on Xolair until February 2019 when the office ran out of samples. Petitioner's doctor noted that Petitioner did much better on the medication, with no exacerbations. Petitioner's doctor testified that despite Petitioner's claims history Petitioner has been compliant with her medication. Petitioner's doctor indicated that he would often provide Petitioner samples of the base medications as well when she came into the office with exacerbations, which might explain the spotty claims history. Petitioner's doctor testified that he could not, however, provide specific

documentation regarding what samples he had given Petitioner and when those samples were given.

Given the above policy and evidence, Petitioner has failed to prove by a preponderance of the evidence that the MHP erred in denying the prior authorization request for Xolair. The MHP only covers Xolair when there is documentation that the member has had a trial and failure of combination therapies for at least 6 months. Here, Petitioner cannot provide such proof due to her spotty claims history and the fact that her doctor's office cannot provide specific documentation regarding the medication given to her as samples. Once Petitioner can establish a trial and failure of combination therapies for at least 6 months, her physician can request Xolair at that time, provided Petitioner meets all of the other requirements listed above.

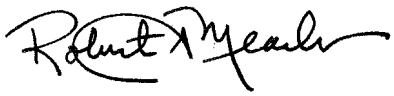
While the undersigned is sympathetic to Petitioner's argument that Xolair is working and approving the medication will save the MHP money in the long run, if the MHP were to approve the medication without Petitioner meeting the above criteria, Medicaid will not pay for the medication. Furthermore, the issue on appeal, and the only issue the undersigned can consider, is whether the MHP's decision was proper at the time it was made, based on the information available at that time. Based on that information, the MHP's decision was proper at the time it was made and must be upheld.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, decides that the MHP properly denied Petitioner's prior authorization request for the medication Xolair.

IT IS THEREFORE ORDERED that:

The Medicaid Health Plan's decision is AFFIRMED.



RM/sb

Robert J. Meade
Administrative Law Judge
for Robert Gordon, Director
Department of Health and Human Services

NOTICE OF APPEAL: A party 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

DHHS -Dept Contact

Managed Care Plan Division
CCC, 7th Floor
Lansing, MI
48919

Community Health Rep

Meridian Health Plan of Michigan Inc.
Appeals Section
PO Box 44287
Detroit, MI
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Authorized Hearing Rep.

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Petitioner

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