[redacted]
[redacted] MI [redacted]

Date Mailed: September 8, 2023
MOAHR Docket No.: 23-004059
Agency No.: [redacted]
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 Petitioner's request for a hearing.

After due notice, a telephone hearing was held on August 23, 2023. Jennifer Smith, registered nurse (RN)/Clinical Appeals Nurse with Eversana, appeared and testified on Petitioner's behalf. Bonnie Pratt, Appeals Coordinator, appeared and testified on behalf of Blue Cross Complete Health Plan, the Respondent Medicaid Health Plan (MHP). Dr. Donald Beam also testified as a witness for Respondent.

During the hearing, Petitioner submitted an evidence packet that was admitted into the record without objection as Petitioner's Exhibits A-N.

Respondent also submitted an evidence packet that had not been previously provided to Petitioner's representative. However, it was subsequently admitted without objection as Respondent's Exhibits #1-3 and A-M after Petitioner's representative had an opportunity to review the documentation. Petitioner's representative also declined an opportunity to leave the record open so that she could submit a written response to Respondent's exhibits.

ISSUE

Did Respondent properly deny Petitioner's request for Prolastin-C liquid infusion augmentation therapy?

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 who is enrolled in the Respondent MHP. (Respondent's Exhibit #1, page 1; Respondent's Exhibit A, page 1).

2. On or about March 20, 2023, Respondent received a prior authorization request for Prolastin-C liquid infusion augmentation therapy submitted on Petitioner's behalf by her doctor. (Respondent's Exhibit A, page 1; Respondent's Exhibit B, pages 1-20).

3. In part, that request indicated that Petitioner has been diagnosed with Alpha-1-antitrypsin deficiency (AATD) with panlobular emphysema, and that she has a PiMZ AAT phenotype. (Respondent's Exhibit B, pages 1, 5).

4. On March 21, 2023, Respondent sent Petitioner written notice that the prior authorization request had been denied. (Respondent's Exhibit C, pages 1-12).

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

> **This request is denied:** according to our Alpha-1 Proteinase Inhibitors (Human) Prior Authorization Criteria.
> The request submitted by your doctor does not meet all or some of our criteria for PROLASTIN C 1,000 MG/20 ML VL. In order for us to approve this drug, the following criteria would also need to be met:
>
> - You have a genetic phenotype of PiMZ, so you are not a candidate for Prolastin-C treatment. Phenotype PiZZ, PiSZ, PiZ(null) or Pi(null)(null) are the only phenotypes that are eligible for treatment.
> - Your forced expiratory volume in 1 second (FEV1) needs to be 65% of predicted or less.
>
> If you think you meet the missing criteria listed above, please ask your doctor to send us supporting information. This information can

> include more medical history and guideline information for your condition.
>
> Our Alpha-1 Proteinase Inhibitors (Human) Prior Authorization Criteria is available upon request.. [sic]

Respondent's Exhibit C, page 3

6. On April 26, 2023, Petitioner, through the supplier of Prolastin-C, filed an Internal Appeal with Respondent regarding that decision. (Respondent's Exhibit F, pages 1-94).

7. In that Internal Appeal, Petitioner's representative wrote in part:

> **Due to her declining respiratory health, [Petitioner] would like to begin Prolastin-C augmentation therapy to prevent further lung damage this deficiency will cause.** It is her provider's professional judgment that Prolastin-C is the most appropriate treatment for [Petitioner].
>
> * * *
>
> Alpha-1 antitrypsin deficiency (AATD) is a genetic condition that raises the risk for the development of pulmonary disease and in some cases liver disease. AAT deficiency is caused by a mutation in the SERPINA1 gene. The production of AAT in individuals with the mutation is dependent on the allele type. There are three alleles for the AAT gene: M, S, and Z with autosomal codominant inheritance. The Z mutation is a deficiency allele (version of the gene) that traps AAT in the liver and reduces the quantity in the blood- causing a severe decrease in AAT. Risks for lung disease, and to a lower extent liver disease, are increased by this genotype. (Gulhar R, 2022)
>
> Prolastin-C is a life sustaining biological product administered by intravenous infusion. It is FDA approved and has been used since 1987 for treating Alpha-1 Antitrypsin Deficiency. Although there is no cure, it is very appropriate for treatment of this genetic

> disease. Augmentation therapy is needed indefinitely. **Prolastin-C will not improve lung function but instead it slows the progression of the disease, reduces exacerbation frequency, and improves patient quality of life. This is extremely important for [Petitioner] as she has already experienced a significant DECREASE in her FEV1 over the last 3 years.** If left untreated, the disease progression may lead to the need for a lung transplant or an untimely death.
>
> Based on the information provided above I ask that you please reconsider your previous decision and grant approval.

Respondent's Exhibit F, page 3

1. As part of that Internal Appeal, Petitioner's representative also included medical records for Petitioner and reference materials regarding Prolastin-C. (Respondent's Exhibit F, pages 4-94).

2. One article included specifically addressed the pros and cons of augmentation therapy for individuals with the PiMZ genotype, noting in part that, while it is possible that individuals with the genotype may benefit from the therapy, current guidelines do not recommend it and there is a lack of evidence supporting the benefits of augmentation. (Petitioner's Exhibit L, pages 1, 10).

3. Respondent sent the Internal Appeal to a specialist in pulmonary disease for review. (Respondent's Exhibit H, page 1).

4. That reviewer subsequently concluded that the requested Prolastin-C is not medically necessary, stating in part:

> The member does not have a phenotype for which Prolastin is indicated. The member has MZ phenotype, which is not indicated for this drug. The member has normal pulmonary function tests and CT without findings of emphysema.

Respondent's Exhibit I, page 1

5. On April 28, 2023, Respondent sent Petitioner written notice that her Internal Appeal was denied. (Petitioner's Exhibit C, page 1; Respondent's Exhibit J, pages 1-9).

6. With respect to the reason for the decision, the notice stated in part:

> You are [redacted] years old. You have a lung problem. (Alpha-1-antitrypsin deficiency with panlobular emphysema). Your doctor wants to treat you with a medicine. (PROLASTIN C 1,000 MG/20 ML VL, quantity of 460 for 28 days 12 total fills). Your case was reviewed by a specialist. (Pulmonologist). This medicine is not approved for use in your condition. (Phenotypes PiMZ or PiMS are not candidates for treatment with Alpha1-Proteinase Inhibitors). The request is therefore denied. If you have questions, please talk to your doctor. (We used Alpha-1 Proteinase Inhibitors (Human) Prior Authorization Criteria, in making this decision).
>
> Our decision is final. If you don't agree with our final decision, you have the right to request an external review or Medicaid Fair Hearing. Your request for a Medicaid Fair Hearing must be made within 120 calendar days of receiving our final decision.

Respondent's Exhibit J, page 1

7. On May 15, 2023, Petitioner filed a request for external review with the Department of Insurance and Financial Services (DIFS). (Petitioner's Exhibit B, page 5; Respondent's Exhibit K, page 6).

8. The Director of DIFS then assigned the case to an independent review organization, Maximus, who recommended that the denial be upheld. (Petitioner's Exhibit B, pages 5, 9; Respondent's Exhibit K, pages 6, 10).

9. With respect to his rationale, the report made regarding the review stated in part:

> The physician consultant explained that based on the available information, there are insufficient information to support the requested Prolastin C as medically necessary for the treatment of this member's condition. The consultant noted that the member was diagnosed with AAT deficiency heterozygous variant MZ, typically characterized by mild-to-moderate reductions in AAT levels, and rarely

requiring augmentation therapy. The consultant also noted that indeed, the member's AAT levels were 75 mg/dL in 2021, above the "minimum protective" threshold of 57 mg/dL, under which augmentation therapy is considered. The physician consultant indicated that moreover, AAT levels in this range are commonly found in patients with the MZ genotype. The Maximus physician consultant indicated that such MZ heterozygous individuals are generally not candidates for AAT augmentation, as they are not at increased risk for pan-acinar emphysema in the absence of smoking. The physician consultant indicated that the cross-sectional CT imaging in July 2022 showed no evidenced of emphysema. The consultant noted that furthermore, the airway obstruction observed by reduction in FEV1 improved significantly after bronchodilator treatment, which would not occur in the case of emphysema. The physician consultant indicated that on the contrary, these pulmonary function testing results suggest asthma could be at inadequately treated, which causes reversible airway obstruction. The consultant noted that thus, in summary, there was insufficient medical evidence to support Prolastin C therapy as medically necessary for the treatment of this member's condition. (Prolastin-C (alpha1-proteinase inhibitor, human) [Highlights of Prescribing Information]. Research Triangle Park, NC: Grifols Therapeutics, Inc; August 2016. Stoller JK, et al. Alpha1-antitrypsin deficiency. Lancet. 2005;365(9478):2225-2236. McElvaney GN, et al. Clinical considerations in individuals with α1-antitrypsin PI*SZ genotype. Eur Respir J. 2020;55(6):1902410. Agusti A, et al. *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: 2020 Report.* GOLD Program; 2020. American Thoracic Society, European Respiratory Society. American Thoracic Society/European Respiratory Society statement: Standards for the diagnosis and

management of individuals with alpha-1 antitrypsin deficiency. *Am J Respir Crit Care Med.* 2003;168(7):818-900. Marciniuk DD, et al. Alpha-1 antitrypsin deficiency targeted testing and augmentation therapy: A Canadian Thoracic Society clinical practice guideline. *Can Respir J.* 2012;19(2):109-116.)

The Maximus physician consultant indicated that the Health Plan's criteria are consistent with standard of care criteria. The physician consultant also indicated that the member did not meet criteria for coverage of Prolastin-C 1,000 mg/20 mL VL, #460.

Pursuant to the information set forth above and available documentation, the Maximus physician consultant determined that Prolastin-C 1,000 mg/20 mL VL, #460 is not medically necessary for treatment of the member's condition.

Petitioner's Exhibit B, pages 3-4
Respondent's Exhibit K, pages 14-15

10. Accepting that recommendation, the Director of DIFS subsequently upheld Respondent's decision. (Petitioner's Exhibit B, page 9; Respondent's Exhibit K, page 10).

11. On July 12, 2023, the Michigan Office of Administrative Hearings and Rules (MOAHR) received the request for a Medicaid Fair Hearing filed by Petitioner in this matter regarding Respondent's decision. (Petitioner's Exhibit A, pages 1-6; Respondent's Exhibit K, pages 16-129).

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, January 1, 2023 version
Medicaid Health Plan Chapter, pages 1, 4
(Underline added for emphasis)

As allowed by the above policy and its contract with the Department, the MHP has chosen to use its own prior authorization requirements, utilization management, and review criteria.

Specifically, as explained by Respondent's witness and demonstrated by its exhibits, regarding Alpha-1 Proteinase Inhibitors like the one requested in this case, the applicable prior authorization criteria provides in part:

Initial Authorization:

- Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level < 11 micromol/L [approximately 57 mg/dL using nephelometry or 80mg/dl by radial immunodiffusion]).

- Documentation was submitted indicating the member has undergone genetic testing for AAT deficiency and is classified as phenotype PiZZ, PiSZ, PiZ(null) or Pi(null)(null)[NOTE: phenotypes PiMZ or PiMS are not candidates for treatment with Alpha1-Proteinase Inhibitors]

- Documentation was submitted (member's pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FEV1] < 65% of predicted), or provider has documented additional medical information demonstrating medical necessity

- Documentation was submitted indicating member is a non-smoker or an ex-smoker (eg.smoking cessation treatment)

- Documentation of the member's current weight

- The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage

- If the medication request is for an Alpha1-Proteinase Inhibitor (human) product other than Prolastin-C, the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C totreat their medical condition

Respondent's Exhibit G, page 1

Here, as discussed above, Respondent denied Petitioner's prior authorization request pursuant to the above policy and on the basis that Petitioner's has the PiMZ genotype and is therefore not a candidate for treatment with Alpha1-Proteinase Inhibitors.

In appealing that decision, Petitioner has the burden of proving by a preponderance of the evidence that Respondent erred. 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 policy and evidence in this case, Petitioner has failed to satisfy her burden of proof and Respondent's decision must be affirmed. Respondent, as permitted by its contract and the MPM, has developed specific utilization review criteria, consistent with all applicable published Medicaid coverage and limitation policies, regarding Alpha1-Proteinase Inhibitors like the one requested by Petitioner, and Petitioner undisputedly does not meet that required criteria given her identified genotype. Moreover, while Petitioner's representative testified that there is a gap in knowledge regarding the requested treatment and that Petitioner; who has significant medical issues and may benefit from it, Respondent's approved criteria is both clear and, as found by the independent reviewer for DIFS and conceded by Petitioner's representative, consistent with current guidelines, which do not recommend augmentation therapy for individuals with the PI*MZ genotype.

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 for Prolastin-C liquid infusion augmentation therapy.

IT IS, THEREFORE, ORDERED that:

Respondent's decision is **AFFIRMED.**

Steven Kibit

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

PROOF OF SERVICE

I certify that I served a copy of the foregoing document upon all parties and/or attorneys, to their last-known addresses in the manner specified below, this 8th day of September 2023.

S. James

S. James
Michigan Office of Administrative Hearings and Rules

Via Electronic Mail:

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