[redacted]
[redacted], MI [redacted]

Date Mailed: June 22, 2022
MOAHR Docket No.: 22-002101
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 and 42 CFR 431.200, *et seq*., following Petitioner's request for a hearing.

After due notice, a hearing was held on June 16, 2022. Petitioner appeared and testified on his own behalf. Wilma Martini, Clinical Pharmacist for Magellan Medicaid Administration, represented Respondent, Michigan Department of Health and Human Services (MDHHS or Department).

ISSUE

Did the Department properly deny Petitioner's request for prior authorization of the medication Methamphetamine?

FINDINGS OF FACT

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

1. Petitioner is a Medicaid beneficiary who has been diagnosed with Cyclothymic Disorder; Attention-Deficit Hyperactive Disorder (ADHD), combined type; and Mixed Obsessive Thoughts and Acts. (Exhibit A, pp 1, 15; Testimony).

2. On May 3, 2022, Petitioner's provider sought prior authorization for the medication Methamphetamine for Petitioner. (Exhibit A, pp 42-74; Testimony).

3. Methamphetamine is an excluded product under Michigan Medicaid, and it is not listed on the Michigan Pharmaceutical Product List (MPPL). (Exhibit A, pp 1, 78-82; Testimony).

4. On January 8, 2022, the Department made an exception to the exclusion policy for Petitioner and Methamphetamine was approved for three (3) months. (Exhibit A, p 1; Testimony).

5. The May 3, 2022 prior authorization request for Methamphetamine was for a higher dose (30 mg total daily dose) than approved under the exception in January 2022. The requested dose was also beyond the FDA recommended maximum dose of 20-25 mg total per day. (Exhibit A, pp 1, 78-82; Testimony).

6. On May 4, 2022, Petitioner's prior authorization request was reviewed by Dr. Jeanne Kapenga, a state physician reviewer, who denied the request for 30 mg of Methamphetamine as the dose exceeded the FDA guidelines and was considered excessive. Petitioner's physician was notified of the denial. (Exhibit A, pp 75-76; Testimony).

7. On May 4, 2022, an Adequate Action Notice of Denial was sent to Petitioner. (Exhibit A, p 77; Testimony).

8. On May 16, 2022, Petitioner's Request for Hearing was received by the Michigan Office of Administrative Hearings and Rules. (Exhibit A, pp 2-41).

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.

The Social Security Act § 1927(d), *42 USC 1396r-8(d)*, provides as follows:

> (d) LIMITATIONS ON COVERAGE OF DRUGS. –
>
> (1) PERMISSIBLE RESTRICTIONS. –
>
> (A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).
>
> (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if –
>
> (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));
>
> (ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) LIST OF DRUGS SUBJECT TO RESTRICTION. – The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(K) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

* * *

(4) REQUIREMENTS FOR FORMULARIES. — A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation

(available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) REQUIREMENTS OF PRIOR AUTHORIZATION PROGRAMS. — A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval –

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

42 USC 1396r-8(k)(6) **Medically accepted** indication -

The term “**medically accepted** indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the

compendia described in subsection (g)(1)(B)(i) of this section.

The Medicaid Provider Manual indicates, in relevant part:

SECTION 7 – MICHIGAN PHARMACEUTICAL PRODUCT LIST

The Michigan Pharmaceutical Product List (MPPL) identifies the pharmaceutical products that are covered by MDHHS. The MPPL pharmaceutical product coverages may vary by MDHHS program or be limited by age, clinical parameters, and/or gender. The Point of Sale pharmacy claim adjudication also provides coverage information related to a specific beneficiary or prescription.

The MPPL is posted on the PBM's website. (Refer to the Directory Appendix for website information.) Providers must refer to the MPPL for the additions and deletions of drug products. Specific notification of changes will not be issued.

7.1 NOTIFICATION OF NEW OUTPATIENT DRUGS

MDHHS receives weekly, comprehensive new information about outpatient drugs from First DataBank. Manufacturers are not required to submit notification of new drug products. New drug products are required to be reviewed by the Pharmacy and Therapeutics (P&T) committee.

Most drug products are required to be on the market for six months prior to review. Products with a “priority” FDA rating may be reviewed earlier than the six month requirement.

7.2 APPROVED LABELERS

MDHHS reimburses MPPL products distributed by approved Labelers who have signed rebate agreements with the Centers for Medicare & Medicaid Services (CMS). A list of these approved Labelers is located on the CMS website and identification is by the first five digits of a National Drug Code (NDC). (Refer to the Pharmacy portion of the Directory Appendix for CMS website information.)

Alcohol swabs, condoms, diaphragms, lancets, syringes, aerochambers, spacers, and peak flow meters provided by a pharmacy are covered regardless of the manufacturer’s rebate agreement.

8.2 PRIOR AUTHORIZATION REQUIREMENTS

PA is required for:

- Products as specified in the MPPL. Pharmacies should review the information in the Remarks as certain drugs may have PA only for selected age groups, gender, etc. (e.g., over 17 years).
- Payment above the Maximum Allowable Cost (MAC) rate.
- Prescriptions that exceed MDHHS quantity or dosage limits.
- Medical exception for drugs not listed in the MPPL.
- Medical exception for noncovered drug categories.
- Acute dosage prescriptions beyond MDHHS coverage limits for H2 Antagonists and Proton Pump Inhibitor medications.
- Dispensing a 100-day supply of maintenance medications that are beneficiary-specific and not on the maintenance list.
- Pharmaceutical products included in selected therapeutic classes. These classes include those with products that have minimal clinical differences, the same or similar therapeutic actions, the same or similar outcomes, or have multiple effective generics available.

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8.4 DOCUMENTATION REQUIREMENTS

For all requests for PA, the following documentation is required:

- Pharmacy name and phone number
- Beneficiary diagnosis and medical reason(s) why another covered drug cannot be used
- Drug name, strength, and form
- Other pharmaceutical products prescribed

- Results of therapeutic alternative medications tried
- MedWatch Form or other clinical information may be required

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8.6 PRIOR AUTHORIZATION DENIALS

PA denials are conveyed to the requester. PA is denied if:

- The medical necessity is not established.
- Alternative medications are not ruled out.
- Evidence-based research and compendia do not support it.
- It is contraindicated, inappropriate standard of care.
- It does not fall within MDHHS clinical review criteria.
- Documentation required was not provided.

Medicaid Provider Manual
Pharmacy Section
April 1, 2022, pp 14-17
Emphasis added

Michigan Medicaid Clinical Criteria for Methamphetamine indicates as follows:

ATTENTION DEFICIT/HYPERACTIVITY DISORDER (ADD/ADHD) AGENTS

Eligibility Program: MA, SMP and CSHCS

Length of Authorization: 6 months for fatigue with chemo/radiation; 1 year for all other diagnoses

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Is there any reason that the patient cannot be switched to a preferred medication? Acceptable reasons include:

- Allergy to the preferred medications
- Contraindication or drug to drug interaction with all preferred medications

- History of unacceptable side effects

- Inability to swallow (if non-preferred liquid, dissolvable tabs or chewable tabs is requested)

Has there been a therapeutic failure of a one-month trial with use of ***ONE*** of the preferred agents? Document.

MEDICATION-SPECIFIC INFORMATION TO AID IN THE FINAL DECISION

- **Daytrana®:** Requests for patients under age 6 and over age 17 will require MDHHS review.

- **Adderall XR®:** Quantity limit of two capsules per day for certain strengths (see *Appendix B).* Overrides will require MDHHS review (unless co-pay request) **[MAP: Quantity Limit: IE 15110].**

- **Vyvanse®:**

  - Max daily dosage limit of 80 mg per day across strengths **[MAP: Quantity Limit: IE 2709]**

  - Requests for quantity limit overrides that do **not** exceed the max daily dosage limit which result from dose change, partial fills, scripts filled for small quantities, etc. may be granted for date of service.

  - Requests for quantity limit overrides that do **not** exceed the max daily dosage limit which result from early refill must meet early refill criteria in order for a quantity limit override to be granted (reference the QC).

  - Requests for quantity limit overrides exceeding the max daily dosage limit will require MDHHS review.

- **Desoxyn® (Methamphetamine):** Excluded

- **Strattera®:** Claims submitted for patients under six years of age will deny. Document the current (or more recent) weight and any previous therapies and forward the request to a clinical pharmacist. The clinical pharmacist will use professional judgment with regard to approval or MDHHS review.

Exhibit A, p 78
Bold in original; underline added for emphasis

The Department's Clinical Pharmacist testified that on May 3, 2022, Petitioner's provider sought prior authorization for the medication Methamphetamine for Petitioner. The Department's Clinical Pharmacist indicated that Methamphetamine is an excluded product under Michigan Medicaid, and it is not listed on the Michigan Pharmaceutical Product List (MPPL). The Department's Clinical Pharmacist testified that on January 8, 2022, the Department made an exception to the exclusion policy for Petitioner and Methamphetamine was approved for three (3) months, but the May 3, 2022 prior authorization request for Methamphetamine was for a higher dose (30 mg total daily dose) than approved under the exception in January 2022. The Department's Clinical Pharmacist indicated that the requested dose was also beyond the FDA recommended maximum dose of 20-25 mg total per day. The Department's Clinical Pharmacist testified that on May 4, 2022, Petitioner's prior authorization request was reviewed by Dr. Jeanne Kapenga, a state physician reviewer, who denied the request for 30 mg of Methamphetamine as the dose exceeded the FDA guidelines and was considered excessive. The Department's Clinical Pharmacist indicated that Petitioner's physician was notified of the denial, and on May 4, 2022, an Adequate Action Notice of Denial was sent to Petitioner.

Petitioner testified that he has tried different medications for ADHD but unfortunately none have worked well. Petitioner indicated that the other drugs he has tried have not helped to control his symptoms and allow him to focus and finish tasks. Petitioner indicated that Methamphetamine is working well and allows him to focus and concentrate. Petitioner indicated that he believes the prescribed dose of 30 mg per day would help improve his medical condition.

Based on the evidence presented, Petitioner has failed to prove, by a preponderance of the evidence, that the Department improperly denied his prior authorization request for the medication Methamphetamine. First, Methamphetamine is an excluded drug in Michigan Medicaid and is not on the MPPL. And, while the Department did allow an exception for the drug for Petitioner in January 2022, that exception was within the FDA recommended dosage range. The dosage range requested here is beyond that recommended by the FDA and as indicated above, policy provides, "Prescriptions that exceed MDHHS quantity or dosage limits" are not covered. The Department relies on the FDA to set dosage limits and the requested dosage here is beyond those limits. Accordingly, the Department's denial is proper based on the submitted information.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, finds that the Department properly denied coverage for the medication Methamphetamine.

IT IS THEREFORE ORDERED that:

The Department's decision is **AFFIRMED**.

RM/tem

Robert J. Meade
Administrative Law Judge

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

Via Electronic Mail:

DHHS Dept Contact
Trish Bouck
Quality Assessment & Improvement
Capitol Commons Center
400 S. Pine Street, 5th Floor
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DHHS Department Rep.
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Via First Class Mail:

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