

## **ISSUE**

**Did Respondent properly deny Petitioner's prior authorization request for methamphetamine?**

## **FINDINGS OF FACT**

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

- 1. MMA contracts with the Department to review prior authorization requests for specified medications. (Testimony of Respondent's representative).**
- 2. On March 29 2024, MMA received a prior authorization request for methamphetamine submitted on Petitioner's behalf by Dr. Jordan Standlee, M.D. (Exhibit A, pages 11-34).**

3. The prior authorization request and attached medical documentation indicated that Petitioner has been diagnosed with narcolepsy, obstructive sleep apnea, and chronic fatigue syndrome. (Exhibit A, page 12).
4. They also indicated that Petitioner had previously tried other medications, including Wakix and Adderall, but there was no indication that those medications had been ineffective. (Exhibit A, pages 12, 14).
5. The Progress Notes from Petitioner's most recent visit with Dr. Standlee on September 7, 2023, also provided that Petitioner reported that a combination of Wakix and Adderall had been very helpful. (Exhibit A, page 15; Testimony of Petitioner).
6. Methamphetamine is not listed on the Michigan Pharmaceutical Product List and could not be unilaterally approved by MMA. (Testimony of Respondent's representative).
7. MMA therefore forwarded the request to the Department for a review by a Department physician. (Testimony of Respondent's representative).
8. On April 1, 2024, the Department physician reviewed the request and determined that it should be denied because it did not meet criteria for approval. (Exhibit A, page 35).
9. MMA then sent Petitioner's doctor an electronic notice of denial. (Exhibit A, page 35).
10. On April 1, 2024, MMA also sent Petitioner written notice that her prior authorization request for methamphetamine had been denied because it did not meet criteria. (Exhibit A, pages 36-40).
11. On April 15, 2024, the Michigan Office of Administrative Hearings and Rules (MOAHR) received the request for hearing filed by Petitioner in this matter with respect to the denial of her request. (Exhibit A, pages 3-9).

## 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), also 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 restriction 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 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 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 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.

- (<sup>5</sup>) 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).

*Exhibit A, pages 42-44*

The Department is therefore authorized by federal law to develop both a formulary of approved prescriptions and a prior authorization process.

It has done so and, with respect to pharmaceutical products like the one requested in this case, the Department generally limits coverage to those products listed as covered on the Michigan Pharmaceutical Product List (MPPL):

#### 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.

*MPM. April 1, 2024 version  
Pharmacy Chapter, page 15*

Moreover, while products not listed on the MPPL may be covered, prior authorization is required and the submitting provider must document both what other drugs have been tried and why a covered drug cannot be used:

## SECTION 8 - PRIOR AUTHORIZATION

### 8.1 PRIOR AUTHORIZATION PROCESSOR

The MDHHS PBM processes prior authorizations (PAs). Refer to PBM's Pharmacy Claims Processing Manual for PA procedures. (See Directory Appendix for contact information.) Authorization to override denial edits must be obtained from the PBM.

Do not call the PBM's Call Centers for:

- Supplies billed by Medical Suppliers, including enteral formula and Total Parenteral Nutrition (TPN), since these are only reimbursed to a Medical Supplier provider. Contact the MDHHS Program Review Division for PA. (Refer to the Directory Appendix for contact information.)
- Information about the member's MHP. The provider must contact the MHP to obtain their policies.

### 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.

\* \* \*

## **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

If prior authorization is being submitted for an item related to a clinical trial, PA requests must also include a completed and signed Attestation to the Appropriateness of the Qualified Clinical Trial form (BPHASA-2210). Refer to the Forms Appendix for a copy of BPHASA-2210.

*MPM. April 1, 2024 version  
Pharmacy Chapter, pages 1617*

In reviewing prior authorization requests pursuant to its contract with the Department, MMA utilized the below criteria for non-formulary medications:

#### NON-FORMULARY PRIOR AUTHORIZATION REQUESTS

Length of Authorization: Up to 1 year

#### CRITERIA TO APPROVE

- Requests for non-formulary medications (i.e. medications excluded from coverage) must include clinical rationale for why the product is more appropriate for the patient than a similar formulary product
- Non-formulary requests may be reviewed by MDHHS physicians for medical necessity and appropriateness

*Exhibit A, page 41*

Here, MMA received a request for methamphetamine submitted on Petitioner's behalf by her doctor and which indicated that Petitioner has been diagnosed with narcolepsy, obstructive sleep apnea, and chronic fatigue syndrome.

Respondent's representative testified that, pursuant to the above criteria, the request could not be approved by MMA given that methamphetamine is not listed on the MPPL and therefore non-formulary, and that it had to be reviewed by a Department physician for medical necessity. She also testified that the Department physician reviewed the request and determined that it should be denied.

In response, Petitioner testified that, after reviewing what was submitted, she would expect that the prior authorization request would be denied given the incomplete information submitted. She also testified that she has been prescribed, and received, methamphetamine in the past following treatment at the Mayo Clinic, and that, while it presents its own side effects, it is the only thing that has worked for her. She further testified that, while the combination of Wakik and Adderall helped temporarily, it is not effective. According to Petitioner, she was not able to see Dr. Standlee after the visit in

September of 2023 because he is leaving the practice, and that she is in the process of getting a new doctor.

Petitioner bears the burden of proving by a preponderance of the evidence that Respondent erred in denying her prior 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 available information and applicable policies in this case, Petitioner has failed to meet her burden of proof and the Respondent's decision must be affirmed.

As discussed above, the Department has been authorized by federal law to develop both a formulary of approved prescriptions and a prior authorization process; it has done so; and, with respect to methamphetamine, it has restricted approval to cases where other, covered drugs are ineffective and methamphetamine is medically necessary.

Here, given the record, Petitioner has not demonstrated such medical necessity. Petitioner may have been prescribed methamphetamine in the past, but that alone is insufficient for approval now, and the review in this case is based on the information submitted.

The submitted information included notes from Petitioner's most recent medical appointment in which it was expressly stated that a combination of Wakix and Adderall, both covered drugs under the MPPL, has been effective. Similarly, the prior authorization form itself listed Wakix and Adderall as medications previously tried for Petitioner's condition without any indication that those medications had been ineffective or failed, despite the form directing the prescriber to do so.

Moreover, while Petitioner testified that the information submitted is incomplete or outdated, her testimony is unsupported; MMA was justified in relying on what was provided; and 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.

To the extent Petitioner has additional or updated information to provide regarding her need for methamphetamine, she and her provider can always request the drug again in the future along with that information. With respect to the issue in this case however, Respondent's decision is affirmed given the information available at the time.

**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**.