## ISSUE

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

## 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 Major depressive disorder, recurrent, severe without psychotic features; and Attention-deficit hyperactivity disorder (ADHD), predominantly inattentive type. (Exhibit A, pp 2, 13; Testimony)

2. On April 30, 2024, Petitioner's provider sought prior authorization for the medication Jornay PM for Petitioner. (Exhibit A, pp 7-15; Testimony)

3. Jornay PM is a non-preferred medication on the Michigan Preferred Drug List (PDL). (Exhibit A, pp 2, 23; Testimony)

4. Per Michigan Medicaid Clinical and PDL Criteria, non-preferred medications can only be approved if there is a failure of one month with one preferred medication, or a history of unacceptable side effects, or contraindication or drug to drug interaction with the preferred medication, or an allergy to the preferred medication. (Exhibit A, p 22; Testimony)

5. Because Jornay PM could not be approved with the clinical information submitted, the PA request was referred to a physician reviewer at the State of Michigan, who upheld the denial, stating, "Denied; non-preferred, please review options for preferred medications." (Exhibit A, p 2; Testimony)

6. On April 30, 2024, an Adequate Action Notice of denial was sent to Petitioner and Petitioner's prescriber was notified of the denial. (Exhibit A, pp 16-21; Testimony)

7. On May 9, 2024, Petitioner's request for hearing was received by the Michigan Office of Administrative Hearings and Rules. (Exhibit A, p 5)

## 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:

> 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).
>
> 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.

(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 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).

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, 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.

* * * *

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; and

- MedWatch Form or other clinical information may be required.

* * * *

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.

Michigan Medicaid Clinical Criteria for Jornay PM indicates as follows:

CENTRAL NERVOUS SYSTEM DRUGS: DRUGS FOR ADHD

(PDL Class - see MICHIGAN PREFERRED DRUG LIST)

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

CRITERIA TO APPROVE (PDL NON-PREFERRED)

- Allergy to the preferred medications; OR
- Contraindication or drug to drug interaction with the preferred medications; OR
- History of unacceptable side effects; OR
- Therapeutic failure of one month with one preferred medication; OR

- Allow PDL non-preferred liquid formulations to be approved if patient has swallowing difficulties.

* * * *

*Exhibit A, p 22*

The Department's Sr. Clinical Pharmacist testified that on April 30, 2024, Petitioner's provider sought prior authorization for the medication Jornay PM for Petitioner. The Department's Sr. Clinical Pharmacist indicated that Jornay PM is a non-preferred medication on the Michigan Preferred Drug List and per Michigan Medicaid Clinical and PDL Criteria, non-preferred medications can only be approved if there is a failure of one month with one preferred medication, or a history of unacceptable side effects, or contraindication or drug to drug interaction with the preferred medication, or an allergy to the preferred medication. The Department's Sr. Clinical Pharmacist testified that because Jornay PM could not be approved with the clinical information submitted, the PA request was referred to a physician reviewer at the State of Michigan, who upheld the denial, stating, "Denied; non-preferred, please review options for preferred medications." The Department's Sr. Clinical Pharmacist indicated that on April 30, 2024, an Adequate Action Notice of denial was sent to Petitioner and Petitioner's prescriber was notified of the denial.

Petitioner's AHR testified that she was aware of the preferred medications but specifically requested this medication because with her ADHD Petitioner struggles to get up and going in the morning. Petitioner's AHR indicated that with Jornay PM, Petitioner would take the medication at night, but it would be effective in the morning when she awoke, allowing her to function better.

In response, the Department's Sr. Clinical Pharmacist indicated that the rationale for prescribing Jornay PM for Petitioner was included in the documentation reviewed by the State's physician reviewer and the reviewer still denied the medication for failing to meet the non-preferred drug criteria.

Based on the evidence presented, Petitioner has failed to prove, by a preponderance of the evidence, that the Department improperly denied the prior authorization request for the medication Jornay PM. As indicated above, Jornay PM is a non-preferred medication. Non-preferred medications are only approved if there is a failure of one month with one preferred medication, or a history of unacceptable side effects, or contraindication or drug to drug interaction with the preferred medication, or an allergy to the preferred medication. Here, none of those criteria were met per the submitted documentation. Furthermore, while Petitioner's provider has a good reason for prescribing the medication, there is no exception in the criteria for such a rationale. Petitioner can resubmit the request with documentation showing she has met one or more of the above criteria. 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 Jornay PM.

**IT IS THEREFORE ORDERED** that:

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