ISSUE

Did the Department properly deny Petitioner's request for prior authorization (PA) of Adderall XR?

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 is over the age of REDACTED. (Exhibit A; Testimony.)

2. On or about February 28, 2023, Petitioner's treating provider submitted a PA for Adderall XR for Petitioner's diagnosis of attention and concentration deficit. (Exhibit A; Testimony.)

3. Medicaid guidelines provide that Adderall XR for patients who are REDACTED years of age or older require a specific diagnosis of ADD/ADHD that has been confirmed via a comprehensive evaluation and/or standard assessment tool and MAPS has been reviewed. (Exhibit A; Testimony.)

4. On February 28, 2023, after clinical review of Petitioner's PA request for Adderall XR, Petitioner's request was denied for not meeting criteria for authorization. The decision was based on the Petitioner not having a diagnosis of ADD/ADHD and not having a diagnosis of ADD/ADHD being confirmed by a comprehensive evaluation and/or standard assessment tool. (Exhibit A; Testimony.)

5. On February 28, 2023, an Adequate Action Notice of denial was sent to Petitioner informing her that the request for Adderall XR had been denied. The Notice included Petitioner's appeal rights. (Exhibit A; Testimony.)

6. On April 10, 2023, the Michigan Office of Administrative Hearings and Rules, received from Petitioner, a request for an administrative hearing. (Exhibit A.)

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 on the list 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 addresses prior-authorization requirements as follows:

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 MDCH quantity or dosage limits.
- Medical exception for drugs not listed in the MPPL.

- Medical exception for noncovered drug categories.
- Acute dosage prescriptions beyond MDCH 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 MDCH clinical review criteria.
- Documentation required was not provided.[1]

The Michigan Medicaid Clinical and PDL Criteria for Adderall XR provides, in pertinent part:

Diagnosis to approve:

- ADD/ADHD (PDL criteria apply):
-
- Ages ≥ 18 (new onset adult ADD/ADHD): Approve if the diagnosis has been confirmed via a comprehensive evaluation and/or standard assessment tool and MAPS has been reviewed.[2]

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

The Department's clinical pharmacist testified that Petitioner's physician submitted a PA on Petitioner's behalf for Adderall XR for a diagnosis of attention and concentration deficit. The Department's clinical pharmacist went on to indicate certain requirements needed to be met in order for Adderall XR to be approved, and that in this case those requirements were not met. Specifically, the requesting physician did not confirm that the patient has a diagnosis of ADD/ADHD, and further, documentation to substantiate the diagnosis were not provided.

The Petitioner testified she needs the medication but is unable to get in for a study for several months. The Petitioner, however, did not provide the medical records needed to show she met the requirements for Adderall XR.

After a thorough review of the record, I have determined the Petitioner did not meet the eligibility criteria as defined in the Department's policy, and thus, the Department's denial is proper. The Petitioner can always have their physician submit a new prior authorization request.

[1] Medicaid Provider Manual, Pharmacy, January 1, 2023, pp 16-18.
[2] Exhibit A, p 33.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, must find that the Department was within its legal authority to deny coverage for the medication sought.

IT IS THEREFORE ORDERED that:

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