

ISSUE

Did Respondent properly deny Petitioner's prior authorization request for the medications dextroamphetamine-amphetamine and Vyvanse?

FINDINGS OF FACT

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

1. Prime Therapeutics contracts with MDHHS to review prior authorization requests for specified medications. (Testimony.)
2. On February 21, 2025, Prime Therapeutics processed a prior authorization request from Dr. Vijayakumar, who specializes in neurology. The request was for the product Vyvanse for a diagnosis of narcolepsy for Petitioner. (Exhibit B; Testimony.)
3. On February 22, 2025, Prime Therapeutics denied Petitioner's request for Vyvanse as medication treatment history did not reconcile with MAPS with multiple stimulants and doses in use simultaneously and/or overlapping. (Exhibit B.)
4. On February 24, 2025, an Adequate Action Notice was sent to Petitioner denying Petitioner's request for Vyvanse. (Exhibit B.)
5. On March 13, 2025, Prime Therapeutics processed a prior authorization request from Dr. Vijayakumar, who specializes in neurology. The request was for the product dextroamphetamine-amphetamine for a diagnosis of narcolepsy for Petitioner. (Exhibit A; Testimony.)
6. On March 14, 2025, Prime Therapeutics denied Petitioner's request for dextroamphetamine-amphetamine for not including a MSLT sleep study. The request was then forwarded to the State of Michigan for review. (Exhibit A; Testimony.)
7. On March 17, 2025, Petitioner's request for dextroamphetamine-amphetamine was denied by the State of Michigan for not meeting approval criteria as the request was missing a MSLT study with interpretation. (Exhibit A; Testimony.)
8. On March 17, 2025, an Adequate Action Notice was sent to Petitioner, denying Petitioner's request for dextroamphetamine-amphetamine. (Exhibit A; Testimony.)
9. On March 31, 2025, the Michigan Office of Administrative Hearings and Rules received from Petitioner, a request for hearing. (Exhibit A; Exhibit B.)

CONCLUSIONS OF LAW

The Medical Assistance Program was 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.

- (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).¹

Moreover, with respect to pharmaceutical products, the applicable version of the Medicaid Provider Manual (MPM) also provides in part:

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.)

¹ Exhibit A, pp 37-42.

- 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.

* * *

8.6 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.

The PBM reviews the information submitted to determine whether the clinical criteria have been met. If the submitted information does not indicate that the criteria have been met, the PA is then sent to the Office of Medical Affairs in MDHHS for final determination on whether the clinical criteria have been met.²

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

It has also done so with respect to stimulants for non-attention deficit disorders, with an initial review conducted by Prime Therapeutics and any secondary, final review conducted by MDHHS.

Specifically, with respect to stimulants for non-attention deficit disorders like Vyvanse, the Michigan Medicaid Clinical and PDL Criteria requires in part:

Toxicology Screening Requirements

- The Department strongly encourages urine toxicology screening when appropriate; AND
- Toxicology results (within 2 months of request) may be required to be submitted in certain cases based on Department review for medical necessity and safety (e.g., MDHHS MAPS review indicates multiple controlled substances and/or multiple providers); AND
- Submission of current toxicology screening results (within 2 months of request) will be required for initial and renewal requests for doses in excess of FDA approved dosages.³

Specifically, with respect to sleep disorder diagnosis, the Michigan Medicaid Clinical and PDL Criteria requires in part:

² Medicaid Provider Manual, Pharmacy, July 1, 2024, pp 16, 18.

³ Exhibit A, p 34.

Sleep Disorder Diagnoses

- **Narcolepsy**
- **Obstructive Sleep Apnea (OSA)**
- **Excessive Daytime Sleepiness**
- **Idiopathic Hypersomnia**
- **Chronic Fatigue – not due to chronic disease**

All initial requests for the above select sleep disorder diagnosis or symptoms must address the following:

...

- Prescriber must submit the following documentation:
 - ...
 - A COPY of confirmatory SLEEP TEST results and interpretation MUST BE SUBMITTED (NOTE: dates of tests must be within last five years) including (see reference table below for confirmatory test examples):
 - BOTH a Polysomnogram (PSG) and Multiple Sleep Latency Testing (MSLT) results and interpretation..⁴

Here, Prime Therapeutics, as the contracted agent for MDHHS received a prior authorization request for Vyvanse and dextroamphetamine-amphetamine submitted on Petitioner's behalf by her doctor.

Respondent's representative testified that pursuant to the above criteria, the requests could not be approved by Prime Therapeutics because the requests did not meet clinical and PDL criteria.

Petitioner argued she had received some of these medications in the past and didn't understand why they were now being denied. Additionally, Respondent argued since her doctor prescribed the medication, the medication should be provided. Last, Petitioner argued she had recently, within the prior 5 years, underwent both sleep studies; and the records should reflect that.

Past receipt or approval does not guarantee future receipt of approval. Additionally, Petitioner failed to provide any policy that required approval of the request based on her doctor's recommendation alone. Petitioner failed to present any evidence to corroborate her claims.

Petitioner bears the burden of proving by a preponderance of the evidence that Respondent erred in denying her prior authorization requests. Moreover, the undersigned

⁴ Exhibit B, p 27.

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 that burden of proof; and the Respondent's decisions must be affirmed.

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 requests.

IT IS, THEREFORE, ORDERED that:

Respondent's decisions are **AFFIRMED**.