

ISSUE

Did Respondent properly deny Petitioner's prior authorization request for the medication 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 of Respondent's representative).
2. On October 18, 2024, Prime Therapeutics received a prior authorization request for Vyvanse submitted on Petitioner's behalf by Petitioner's doctor. (Exhibit A, pages 4-11).

¹ At the time of the action in this case, Prime Therapeutics was known as Magellan Medicaid Administration (MMA).

3. The prior authorization request indicated that Petitioner has been diagnosed with binge-eating disorder. (Exhibit A, page 6).
4. There was also a reference to a therapist diagnosing Petitioner with that disorder, but there was no documentation or indication that a comprehensive evaluation had been performed that confirmed the diagnosis. (Exhibit A, pages 4-11; Testimony of Petitioner; Testimony of Respondent's representative).
5. Based on the lack of a comprehensive evaluation, Prime Therapeutics determined that it could not approve Petitioner's request. (Testimony of Respondent's representative).
6. Prime Therapeutics, therefore, forwarded the request to MDHHS for a review by a Department physician. (Testimony of Respondent's representative).
7. On October 21, 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 12).
8. Prime Therapeutics sent Petitioner's doctor an electronic notice of denial that same day. (Exhibit A, page 12).
9. On October 21, 2024, Prime Therapeutics also sent Petitioner written notice that her prior authorization request for Vyvanse had been denied because it did not meet criteria. (Exhibit A, pages 13-17).
10. On October 29, 2024, MOAHR received the request for hearing filed by Petitioner in this matter with respect to the denial of her request. (Exhibit A, page 3).

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).

Exhibit A, pages 22-24

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

SECTION 1 — GENERAL INFORMATION

Michigan Department of Health and Human Services (MDHHS) administers the fee-for-service (FFS) programs for Medicaid, Healthy Michigan Plan, Children's Special Health Care Services (CSHCS), and Maternity Outpatient Medical Services (MOMS). This chapter, the Michigan Pharmaceutical Product List (MPPL), and the Michigan Preferred Drug List (PDL)/Single PDL comprise program policies and explain coverage and reimbursement for the services dispensed and billed by enrolled pharmacies.

* * *

1.7.A. CARVE-OUT EXCEPTIONS

Select drugs and classes may be carved-out from the respective health plan's reimbursement and paid Medicaid Fee For Service. (Refer to the PBM website listed in the Directory Appendix for a listing of these drug classes.)

Any services paid Fee For Service must follow appropriate guidelines for supporting documentation, including attending, billing, prescribing, referring, rendering and supervising provider requirements

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SECTION 2 - PRESCRIBER REQUIREMENTS

All MDHHS-covered legend and over-the-counter drugs (OTCs), except condoms, require a prescription order by a licensed professional acting within their scope of practice as defined by state and federal laws, rules, and regulations.

Coverage of pharmaceutical products is based on limitations stated in this chapter, the MPPL, and medical necessity. Determination of medical necessity and appropriateness of service is the responsibility of the prescribing physician/provider (prescriber) within the scope of currently accepted medical practice and MDHHS limitations . . .

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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.

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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.

8.6 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.

*MPM, October 1, 2024, version
Pharmacy Chapter, pages 1, 6, 8, 15-16, 18*

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:

Binge Eating Disorder

- Comprehensive evaluation has been performed which confirms the diagnosis of moderate to severe binge-eating disorder, including DSM 5 criteria, physical exam, and any necessary labs; AND
- Patient has been counseled on the benefits of cognitive behavioral therapy (CBT) and referred if appropriate; AND

- Current clinical notes supporting responses to each of the above criteria and describing all diagnoses, current medications, patient symptoms and treatment plan have been submitted; AND
- MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results.

Exhibit A, page 155

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

Respondent's representative testified that pursuant to the above criteria, the request could not be approved by Prime Therapeutics because there was no evidence of a comprehensive evaluation having been performed that confirmed Petitioner's diagnosis of moderate to severe binge-eating disorder, including DSM 5 criteria, physical exam, and any necessary labs.

Respondent's representative also testified that given that finding, Petitioner's request was forwarded to MDHHS for a final determination on whether the clinical criteria had been met. She further testified that the Department physician reviewed the request and determined that it should be denied as it did not meet clinical criteria.

In response, Petitioner testified that she has undergone a comprehensive evaluation, and that it was recently submitted. She also testified that Vyvanse is the only medication that can work for her.

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 that 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 prescriptions for stimulants for non-attention deficit disorders like Vyvanse based on a binge eating disorder, it has specific documentation requirements.

With respect to the current request, it is undisputed that the submitted documentation does not meet those requirements, with the records failing to demonstrate a comprehensive evaluation, including DSM 5 criteria, a physical exam and any necessary labs having been performed that confirmed the diagnosis of moderate to

severe binge-eating disorder. Accordingly, the denial was, therefore, proper as Petitioner did not meet clinical criteria for approval.

To the extent Petitioner has corrected or updated information to provide in support of the request for Vyvanse, then she can always have another prior authorization request submitted in the future along with that information. With respect to the decision at issue in this case, however, Respondent's decision must be affirmed given the available information and applicable policies.

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**.