ISSUE

Did Respondent properly deny Petitioner's prior authorization request for the medication Modafinil?

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 January 17, 2024, MMA received a prior authorization request for the medication Modafinil 200 Mg submitted on Petitioner's behalf by Michelle Schweiger, a Nurse Practitioner (NP). (Exhibit A, pages 5-9).**

3. The prior authorization request and attached medical documentation indicated that Petitioner has been diagnosed with chronic fatigue syndrome and optic neuritis. (Exhibit A, page 8).

4. MMA then forwarded the request to the Department for a review by a Department physician. (Testimony of Respondent's representative).

5. On January 18, 2024, the Department physician reviewed the request and determined that it should be denied because it did not meet criteria for approval given the information submitted. (Exhibit A, page 5).

6. The physician also stated the requested amount exceeded the maximum recommended dosage. (Exhibit A, page 5).

7. MMA then sent Petitioner's doctor an electronic notice of denial. (Exhibit A, page 10).

8. On January 18, 2024, MMA also sent Petitioner written notice that her prior authorization request for Modafinil had been denied because it did not meet criteria. (Exhibit A, pages 11-15).

9. On January 19, 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 3-4).

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.

(^{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 27-29

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 requests for stimulants for non-attention deficit disorder, the Michigan Medicaid Clinical and PDL Criteria at the time of the request in this case provided in part:

> All requests will require MDHHS review EXCEPT those submitted for chronic fatigue due to chronic disease. If criteria has been met for this diagnosis, an approval may be granted.
>
> * * *
>
> PROVIGIL (MODAFINIL) AND NUVIGIL (ARMODAFINIL)
>
> - Diagnosis of narcolepsy; AND
>
> Patient ≥ 18 years old; AND
>
> Patient has experienced > 3 months' duration of symptoms resulting in cognitive, social, occupational, or other significant stress; AND
>
> Other medical conditions (e.g., hypothyroidism) and behavioral health conditions (e.g., depression) with similar symptoms have been actively evaluated along with ongoing treatment optimization; AND
>
> Medical record notes that sedating drugs, marijuana, alcohol, or other substances of abuse have been ruled out as contributing to sleep disorder symptoms; AND
>
> Standard criteria (i.e., DSM-5, ISCD-3) or Epworth scale (score 10) have been utilized to confirm the diagnosis; AND
>
> Failure of improvement with a two-week trial of standard sleep hygiene recommendations; AND
>
> A copy of confirmatory sleep test results and interpretation within the last two years have been submitted to include Polysomnogram (PSG) and Multiple Sleep Latency Testing (MSLT); AND

- Current clinical notes outlining all diagnoses, all medications, description of patient symptoms and treatment plan have been submitted; **AND**
- If female patient of childbearing age (10-50 years of age), patient is not pregnant; **AND**
- MAPS has been checked

Renewal requests:

- Prescriber attests that the patient has benefited from treatment with no adverse effects and continued treatment is medically necessary (if the patient has experienced adverse effects, clinical notes outlining adverse response must be submitted)

- Diagnosis of obstructive sleep apnea (OSA)/obstructive sleep apnea syndrome (OSAS); **AND**
  - Patient ≥ 18 years old; **AND**
  - Patient has experienced > 3 months' duration of symptoms resulting in cognitive, social, occupational, or other significant stress; **AND**
  - Other medical conditions (e.g., hypothyroidism) and behavioral health conditions (e.g., depression) with similar symptoms have been actively evaluated along with ongoing treatment optimization; **AND**
  - Medical record notes that sedating drugs, marijuana, alcohol, or other substances of abuse have been ruled out as contributing to sleep disorder symptoms; **AND**
  - Standard criteria (i.e., DSM-5, ISCD-3) or Epworth scale (score 10) have been utilized to confirm the diagnosis; **AND**
  - Failure of improvement with a two-week trial of standard sleep hygiene recommendations; **AND**
  - A copy of confirmatory sleep test results and interpretation within the last two years have been submitted to include Polysomnogram (PSG) and, if available, Multiple Sleep Latency Testing (MSLT); **AND**
  - Current clinical notes outlining all diagnoses, all medications, description of patient symptoms and treatment plan have been submitted; **AND**
  - If female patient of childbearing age (10-50 years of age), patient is not pregnant; **AND**
  - MAPS has been checked

Renewal requests:

- Prescriber attests that the patient has benefited from treatment with no adverse effects and continued treatment is medically necessary (if the patient has experienced adverse effects, clinical notes outlining adverse response must be submitted)

- Diagnosis of shift work sleep disorder; **AND**
  - Patient ≥ 18 years of age; **AND**
  - Patient is on night shift or rotating shifts; **AND**
  - Patient cannot decrease the number of rotating or night shifts; **AND**
  - History and physical indicates no medical or psychiatric conditions that could be causing the symptoms; **AND**
  - Medical record notes that sedating drugs, marijuana, alcohol, or other substances of abuse have been ruled out as contributing to sleep disorder symptoms; **AND**
  - Patient has any two of the following: insomnia, excessive daytime sleepiness, difficulty concentrating, non-refreshing sleep; **AND**
  - Patient has a 14-day sleep diary documents loss of one to four hours of sleep; **AND**
  - Patient has attempted to use sleep hygiene measures for 14 days or greater without improvement; **AND**
  - Current clinical notes outlining all diagnoses, current medications, description of patient symptoms and treatment plan have been submitted; **AND**
  - If female patient of childbearing age (10-50 years of age), patient is not pregnant; **AND**
  - MAPS has been checked

PROVIGIL® (MODAFINIL)

- Diagnosis of myotonic dystrophy; **AND**
  - Patient ≥ 18 years of age; **AND**
  - Current clinical notes outlining all diagnoses, current medications, description of patient symptoms and treatment plan have been submitted; **AND**
  - MAPS has been checked

Exhibit A, pages 16-18

Here, MMA received a request for Modafinil submitted on Petitioner's behalf by her nurse practitioner that indicated that Petitioner has a diagnosis of chronic fatigue syndrome and optic neuritis, with no chronic disease identified as the cause of Petitioner's chronic fatigue.

Respondent's representative testified that, pursuant to the above criteria, the request could not be approved by MMA given Petitioner's identified diagnosis and that it had to be reviewed by a Department physician. She also testified that the Department physician reviewed the request and determined that it should be denied. She further testified that Modafinil is not approved by the Food and Drug Administration (FDA) for treatment of Petitioner's condition; Petitioner's provider had an opportunity to demonstrate medical necessity for any off-label use; and that nothing more was provided.

In response, Petitioner testified that she has been on Modafinil previously, after it was prescribed by her neurologist; it was helping; and that the only reason it stopped was because of a month gap in her Medicaid coverage mistakenly caused by DHHS. She also testified that her medical providers are trying to figure out her diagnosis, but she has not seen her neurologist recently. She further testified that the nurse practitioner who submitted the prior authorization request is Petitioner's primary care physician, and that the nurse practitioner said more information would be sent in.

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 Modafinil prescribed for non-attention deficit disorders, it has restricted approval without physician review for certain diagnoses.

Here, Petitioner does not have any of those listed diagnoses and, while the Department physician also reviewed the request for an approval based on medical necessity, that physician expressly found that the request should still be denied based on the available information.

Moreover, while Petitioner may have been approved for Modafinil in the past, that alone is insufficient for another approval and the review in this case is based on the information submitted, with no further information submitted in response to the denial.

To the extent Petitioner has additional or updated information to provide regarding her need for Modafinil, 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.**