ISSUE

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

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 March 2, 2022, MMA received a prior authorization request for the medication Spravato submitted on Petitioner's behalf by a Dr. Rajarethinam. (Exhibit A).

3. The prior authorization request and attached medical documentation indicated that Petitioner has been diagnosed with Bipolar I Disorder. (Exhibit A).

4. The request and medical documentation did not indicate a diagnosis of treatment-resistant depression after failure on two different classes of

antidepressants, or a diagnosis of major depressive disorder with acute suicidal ideation or behavior. (Exhibit A; Testimony).

5. Following a review of the request, Dr. Jeanne Kapenga reviewed the request and determined that it should be denied because it did not meet diagnosis criteria of treatment-resistant depression. (Exhibit A; Testimony).

6. On March 4, 2022, MMA also sent Petitioner written notice that her prior authorization request for Spravato had been denied because it did not meet criteria. (Exhibit A; Testimony).

7. On March 14, 2022, the Michigan Office of Administrative Hearings and Rules (MOAHR) received from Petitioner, a request for 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), 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.

(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).'

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 Spravato, the Michigan Medicaid Clinical and PDL Criteria at the time of the request in this case provided in part:

[1] Exhibit A.

Patient has treatment-resistant depression after failure on two different classes of antidepressants; OR Patient has major depressive disorder (MDD) with acute suicidal ideation or behavior?

Here, MMA received a request for Spravato submitted on Petitioner's behalf by her treating physician that indicated Petitioner has a diagnosis of Bipolar I Disorder, but that did not indicate a diagnosis of treatment-resistant depression after failure on two different classes of antidepressants OR a diagnosis of major depressive disorder.

Respondent testified she had received Spravato in the past and further claimed that Medicaid had paid for those prescriptions.

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. Petitioner has failed to present evidence showing she met the criteria for Spravato. Accordingly, Respondent's decision 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 request.

IT IS, THEREFORE, ORDERED that:

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