RICK SNYDER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
Christopher Seppanen
Executive Director

MIKE ZIMMER
DIRECTOR

[redacted]

Date Mailed: July 25, 2016
MAHS Docket No.: 16-004665
Agency No.: [redacted]
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Corey Arendt

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and 42 CFR 431.200 *et seq.,* upon the Petitioner's request for a hearing.

After due notice, a hearing was held on July 14, 2016. The Petitioner appeared and offered testimony on his own behalf. [redacted], Clinical Pharmacist, appeared and offered testimony on behalf of the [redacted] (MMA).

ISSUE

Did the Department properly deny Petitioner's request for prior authorization?

FINDINGS OF FACT

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

1. Appellant is a [redacted] year-old Medicaid beneficiary born [redacted]. (Exhibit B, p. 10).

2. MMA contracts with the Department to review drug prior authorization requests. (Testimony).

3. On April 12, 2016, MMA received a prior authorization request from Dr. [redacted] on behalf of the Petitioner. The request was for Adderall XR to treat a diagnosis of spondylosis of the spine and to help the Petitioner's nervous system. (Exhibit B, pp. 1, 10; Testimony).

4. MMA and a physician reviewer (Dr. [redacted]) reviewed the prior authorization request and determined the request should be denied as the Petitioner did not meet the requirements for Adderall XR. (Exhibit B, pp. 1, 9-10; Testimony).

5. On April 14, 2016, MMA sent notice of the denial to the Petitioner. (Exhibit B, p. 11; Testimony).

6. On April 19, 2016, the Michigan Administrative Hearing System (MAHS) received from the Petitioner a request for hearing concerning the April 14, 2016 MMA denial. (Exhibit B, p. 4; Testimony).

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 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 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 B, pp 17-18.

The Department is therefore authorized by federal law to develop both a formulary of approved prescriptions and a prior authorization process. Moreover, as testified to by its witness, it has done so and it uses the Michigan Medicaid Clinical and PDL Criteria to address prior authorization requests such as Petitioner's.

Here, the Michigan Medicaid Clinical and PDL Criteria developed and used by the Department with respect to Adderall XR requires not only Department approval but also a diagnosis of any of the following:

- Narcolepsy
- ADD/ADHD
- Fatigue with chemotherapy/radiation
- Depression

- Stimulation purposes caused by age or other medications
- Traumatic brain injury (TBI)
- Binge eating disorder (Vyvanse

MMA and the Department denied the prior authorization request submitted on Petitioner's behalf pursuant to the above policies. Specifically, both MMA and the Department's physician reviewer found that the request for Adderall XR did not meet the exception criteria.

In response, Petitioner argued the request was to treat fatigue that was associated with his diagnosis of spondylosis. Even if true, this fact does not meet the exception criteria.

Given the record in this case, Petitioner has failed to meet his burden of proof and MMA's decision must therefore be affirmed.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, decides that the Department properly denied the Petitioner's prior authorization request.

IT IS THEREFORE ORDERED that:

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

CA[redacted]

Corey Arendt
Administrative Law Judge
for Nick Lyon, Director
Department of Health and Human Services

NOTICE OF APPEAL: A party may appeal this Order in circuit court within 30 days of the receipt date. A copy of the circuit court appeal must be filed with the Michigan Administrative Hearing System (MAHS).

A party may request a rehearing or reconsideration of this Order if the request is received by MAHS within 30 days of the date the Order was issued. The party requesting a rehearing or reconsideration must provide the specific reasons for the request. MAHS will not review any response to a request for rehearing/reconsideration.

A written request may be mailed or faxed to MAHS. If submitted by fax, the written request must be faxed to (517) 335-6088; Attention: MAHS Rehearing/Reconsideration Request.

If submitted by mail, the written request must be addressed as follows:

Michigan Administrative Hearings
Reconsideration/Rehearing Request
P.O. Box 30763
Lansing, Michigan 48909-8139

DHHS -Dept Contact

Petitioner

DHHS Department Rep.