RICK SNYDER
GOVERNOR

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

MIKE ZIMMER
DIRECTOR

[redacted]

[redacted]

MAHS Docket No.: 16-000193

[redacted]

ADMINISTRATIVE LAW JUDGE: Steven Kibit

DECISION AND ORDER

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

After due notice, a hearing was held on [redacted]. Petitioner appeared and testified on his own behalf. [redacted], a Clinical Pharmacist with [redacted]), represented the Michigan Department of Health and Human Services (DHHS or Department).

ISSUE

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

FINDINGS OF FACT

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

1. [redacted] contracts with the Department to review prior authorization requests for specified medications. (Testimony of Respondent's representative).

2. On [redacted] received a prior authorization request submitted on Petitioner's behalf by a [redacted] and requesting the medication Adderall for Petitioner. (Exhibit A, pages 6-17).

3. Petitioner and his provider had previously requested the medication through his Medicaid Health Plan (MHP), but they were later advised that the medication is carved out from the MHP's coverage and they would have to request it directly from the Department/[redacted]. (Exhibit A, page 17).

4. In the request to [redacted] noted that Petitioner, who was t[redacted]-years-old at the time of the request, was initially diagnosed with Attention-deficit/hyperactivity disorder (ADHD) in [redacted], when he was under the age of [redacted], and that he has received treatment in the past from the local Community Mental Health. (Exhibit A, page 6).

5. Petitioner's treatment with the local Community Mental Health ended after he aged out of his parents' health care and he only recently became enrolled in his MHP. (Testimony of Petitioner).

6. [redacted], whose specialty is family medicine, also noted that she had confirmed that Petitioner's ADHD still persists and is getting worse. (Exhibit A, page 6).

7. On [redacted] reviewed Petitioner's prior authorization request and noted that it has no record of Petitioner ever being on the requested medication before and that he was initially diagnosed with ADHD in [redacted] and then again in [redacted] by [redacted] (Exhibit A, page 19).

8. During the review, [redacted] also determined that the prior authorization request could not be approved as there was no evaluation by a psychiatrist, psychologist, social worker or licensed counselor after Petitioner turned [redacted] that confirmed the diagnosis of ADHD. (Exhibit A, page 19; Testimony of Department's representative).

9. [redacted] then forwarded Petitioner's request to the Department, whose physician reviewer found that [redacted] must "Deny, last psych evaluation was in [redacted]. Needs current with recommendations". (Exhibit A, page 21).

10. After receiving the response from the physician reviewer, [redacted] sent a notice of denial to [redacted]. (Exhibit A, page 22).

11. On [redacted], it also sent a written notice of denial to Petitioner. (Exhibit A, page 23).

12. On [redacted] [redacted], the Michigan Administrative Hearing System (MAHS) received the request for hearing filed in this matter regarding that denial. (Exhibit 1, pages 1-3; Exhibit A, pages 2-4).

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.

(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 A, pages 25-31

The Department is therefore authorized by federal law to develop both a formulary of approved prescriptions and a prior authorization process. In this case, the Michigan Medicaid program guidelines list criteria for ADHD/ADD (attention deficit hyperactivity disorder/attention deficit disorder) that must be met in order to approve medications:

- **Under Age 3:** Approve if the patient has a pediatric psychiatric or neurological evaluation confirming the diagnosis of ADD / ADHD

- **Ages 3-5:** Approve for diagnosis of ADD / ADHD.

- **Ages 6-7:** No PA required

- **Ages ≥ 18 (continuation of *un*interrupted therapy – < 6 month lapse):** Approve for diagnosis of ADD / ADHD if continuation of uninterrupted therapy has been confirmed by POS history or documentation of uninterrupted therapy has been provided (i.e., chart notes, med review, history, pharmacy claims history, copies of Rx, etc)

- **Ages ≥ 18 (continuation of interrupted therapy – > 6 month lapse):** If the patient was treated as a child for ADD / ADHD and now presents for an extension of that treatment, this should **not** be considered a case of new, adult onset ADD/ADHD. MDDHS review will be required unless the diagnosis of ADD / ADHD has been made by a psychiatrist, clinical (neuro)psychologist (examples of acceptable credentials include but are not limited to LLP, LP, PsyD, PhD), clinical social worker (examples of acceptable credentials include but are not limited to LMSW, LCSW) or licensed/certified counselor (examples of acceptable credentials include but are not limited to LPC, LPCC, CAAC, CADC, CAADC) after turning 18 years old. Any other specialty is not acceptable and

should be forwarded to a clinical pharmacist for possible MDCH review. If MDHHS review is necessary, the following must be documented:

- When the initial diagnosis was made
- When the ADD / ADHD was last treated
- If the patient is still in school, is working or what the social implications of the diagnosis are
- If a current MAPS report has been reviewed, a copy of the report must be included in the patient's medical record at the prescribing physician's office. **A COPY OF THE REPORT IS NOT TO BE INCLUDED WITH THE PA REQUEST** . . .

- **Ages ≥ 18 (new onset adult ADD /ADHD):** MDHHS review will be required unless the diagnosis of ADD / ADHD has been made by a psychiatrist, clinical (neuro)psychologist (examples of acceptable credentials include but are not limited to LLP, LP, PsyD, PhD), clinical social worker (examples of acceptable credentials include but are not limited to LMSW, LCSW) or licensed/certified counselor (examples of acceptable credentials include but are not limited to LPC, LPCC, CAAC, CADC, CAADC) after turning 18 years old. Any other specialty is not acceptable and should be forwarded to a clinical pharmacist for possible MDCH review. If MDHHS review is necessary, the following must be documented:

  - When the initial diagnosis was made
  - When the ADD / ADHD was last treated
  - If the patient is still in school, is working or what the social implications of the diagnosis are
  - If a current MAPS report has been reviewed, a copy of the report must be included in the patient's medical record at the prescribing physician's office. **A COPY OF THE REPORT IS NOT TO BE INCLUDED WITH THE PA REQUEST** . . .

Exhibit A, page 26

Here, [redacted] reviewed the prior authorization request and information provided against the criteria found in the above guidelines and it correctly determined that the information provided was not sufficient to meet the criteria. Petitioner had been diagnosed with and treated for ADHD when he was under the age of eighteen, but, given his history, there was a lapse in therapy greater than six months prior to the request in this case. Consequently, Department review was required unless a diagnosis of ADD/ADHD had

been made by a psychiatrist, clinical psychologist, clinical social worker or licensed/certified counselor after Petitioner turned [redacted]-years-old. In this case, however, the diagnosis was only made by [redacted], whose specialty is Family Medicine and who does not qualify under the above policy. Accordingly, Petitioner's prior authorization request was sent to the Department for a physician review, where the physician reviewer also determined that the Petitioner did not meet the criteria and that a current psychological evaluation with recommendations was required.

Petitioner disagrees with the denial, but he does not dispute the above facts relied upon by Respondent. Moreover, while Petitioner expressed frustration with the process and the amount of time it is taking to get the medication approved, his frustration, while understandable, is insufficient to demonstrate that Respondent erred. Similarly, to the extent Petitioner is dissatisfied with his MHP and his inability to schedule an appointment through the MHP in order to get a current diagnosis of ADHD made by a psychiatrist, clinical psychologist, clinical social worker or licensed/certified counselor, that dissatisfaction is insufficient to meet his burden in this case as his dispute is with the MHP and not with the Respondent here.

Regardless of what remedies may be available through his MHP, the Department's denial in this case was proper based upon the information received with the prior authorization request. Petitioner had a lapse in treatment and, while he attempted to provide the diagnosis required by policy because of that lapse, the diagnosis was not made by a qualified specialist. If Petitioner is able to get such a diagnosis in the future, he can always resubmit his request.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that the Department properly denied Petitioner's prior authorization request for the medication Adderall.

IT IS, THEREFORE, ORDERED that:

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

Steven Kibit

SK/db

Steven Kibit
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

[redacted]

[redacted]

[redacted]