STATE OF MICHIGAN
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
FOR THE DEPARTMENT OF COMMUNITY HEALTH
P.O. Box 30763, Lansing, MI 48909
(877) 833-0870; Fax: (517) 373-4147

IN THE MATTER OF:

[redacted],

Docket No. 14-015006 PHR
Case No. [redacted]

Appellant

_____/

DECISION AND ORDER

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

After due notice, a hearing was held on [redacted]. Appellant appeared and testified on her own behalf. [redacted], Clinical Pharmacist for [redacted] Medicaid Administration (MMA), represented the Michigan Department of Community Health (MDCH or the Department). Appellant alleged that she did not receive the Hearing Summary and Exhibit Packet sent to her from Respondent. An objection to the admission of the Respondent's Exhibit Packet and Hearing Summary was entered on Appellant's behalf. The record was left open until [redacted], to allow Appellant time to receive the respondent's Hearing Summary and Exhibit Packet in the mail and to present additional information or objections in support of her allegations.

ISSUE

Did the Department properly deny the Appellant's request for prior authorization of Modafinil?

FINDINGS OF FACT

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

1. Appellant is a [redacted] year old woman (DOB [redacted]). She is a Medicaid recipient.

2. Appellant meets the criteria for idiopathic hyper-somnolence.

3. On [redacted], Appellant sought prior authorization for treatment with Modafinil (generic for Provigil). (Exhibit A, Page 3)

4. On [redacted], MMA clinical staff processed a request for a prior authorization from Dr. [redacted]. Dr. [redacted] specializes in sleep medicine. Dr. [redacted] requested Modafinil for Appellant for a diagnosis of excessive daytime sleepiness/idiopathic hyper-somnolence for Appellant.

5. On [redacted], MMA denied Appellant's prior authorization request.

6. The request was forwarded to Dr. [redacted], a Physician Reviewer with the State in accordance with contractual requirements. Upon review, Dr. [redacted] denied the request stating: "concur with denial. Does not meet criteria."

7. Dr. [redacted] office was notified of the denial.

8. On [redacted], an Adequate Action Notice of Denial was sent to the Appellant indicating that the reason for the action is it does not meet criteria. The legal basis for this decision is 42 CFR 40.230 (d). (Respondent's Exhibit A, page 21)

9. On [redacted], additional clinical information including a letter of medical necessity was received by MMA from the physician's office, with the same diagnosis.

10. Upon review, Dr. [redacted], a Physician Reviewer with the State, denied the request stating: "denying – no approvable diagnosis."

11. On [redacted], a corrected Notice of Denial was sent to Appellant's physician.

12. On [redacted] Appellant's request for hearing contesting the negative action was received by the Michigan Administrative Hearing System.

13. On [redacted], the hearing was held.

14. At the hearing, Appellant alleged that she did not receive the Hearing Summary and attached documents in the mail.

15. Respondent alleged that the documents were sent via FED EX and she received delivery confirmation for [redacted].

16. Respondent agreed to send the Hearing summary and attached documents to Appellant on [redacted], and provide the Administrative Law Judge with delivery confirmation information by [redacted].

17. Appellant agreed to provide a written statement to the Administrative Law Judge by [redacted], in affirmation of her position and with any objections to Respondent's documents.

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)*, provides as follows:

> 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).
> 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).

42 USC 1396r-8(k)(6) MEDICALLY ACCEPTED INDICATION -

> The term “medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

The Medicaid Provider Manual addresses prior-authorization requirements as follows:

> **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 MDCH quantity or dosage limits.
> - Medical exception for drugs not listed in the MPPL.
> - Medical exception for noncovered drug categories.
> - Acute dosage prescriptions beyond MDCH 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.
>
> * * *

8.4 DOCUMENTATION REQUIREMENTS

For all requests for PA, the following documentation is required:

- Pharmacy name and phone number;
- Beneficiary diagnosis and medical reason(s) why another covered drug cannot be used;
- Drug name, strength, and form;
- Other pharmaceutical products prescribed;
- Results of therapeutic alternative medications tried; and
- MedWatch Form or other clinical information may be required.

* * *

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 MDCH clinical review criteria.
- Documentation required was not provided.

MDCH Medicaid Provider Manual; Pharmacy Section
Version Date: July 1, 2014, pp 14-15

Appellant testified that she has medical necessity for the medication because she has excessive daytime sleepiness/idiopathic hyper somnolence. Appellant alleges that she sleeps all day long and cannot perform activities of daily living adequately without the medication. An [redacted] [redacted] Clinic letter indicates that Appellant's MS LT showed a mean sleep latency of 5.3 minutes and she also fell asleep between net periods. There was one sleep onset REM. She meets the criteria for idiopathic hyper somnolence. (Respondent's Exhibit A, page 3) The study showed objective evidence of excessive daytime sleepiness. (Respondents Exhibit A, page 9)

Respondent testified that the Michigan Medicaid Clinical and PDL Criteria at page 204, indicate that Provigil (Modafinil) has specific diagnosis to be approved. The diagnoses listed to approve Modafinil (a generic of Provigil) are;

> 1) narcolepsy;
> 2) fatigue associated with multiple sclerosis,
> 3) obstructive sleep apnea/obstructive sleep apnea syndrome, confirmed by a sleep study;
> 4) myotonic dystrophy; and
> 5) shift work sleep disorder (which requires MDCH review).
>
> *Michigan Medicaid Clinical and PDL Criteria, (Revised October 8, 2014)*

Since the diagnosis was not approvable preclinical criteria, the product could not be approved. Respondent's Exhibit A, page 1. Therefore, the request was forwarded to Dr. [redacted], a position Reviewer at the state, in accordance with contractual requirements. Upon review, Dr [redacted] denied the request, stating that the medication did not meet the criteria for approval.

This Administrative Law Judge has reviewed the evidence of record. Modafinil is not an approved medication for excessive daytime sleepiness/idiopathic hyper-somnolence. Accordingly, the Department's denial must be upheld as proper based on the submitted information.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, must find that the Department was within its legal authority to deny coverage for the medication sought.

IT IS THEREFORE ORDERED that:

The Department's decision is AFFIRMED.

Landis Y. Lain
Administrative Law Judge
for Nick Lyon, Director
Michigan Department of Community Health

LYL[redacted]

cc: [redacted]

Date Signed: [redacted]

Date Mailed: [redacted]

***** NOTICE *****

The Michigan Administrative Hearing System for the Department of Community Health may order a rehearing on either its own motion or at the request of a party within 30 days of the mailing date of this Decision and Order. The Michigan Administrative Hearing System for the Department of Community Health will not order a rehearing on the Department's motion where the final decision or rehearing cannot be implemented within 90 days of the filing of the original request. The Appellant may appeal the Decision and Order to Circuit Court within 30 days of the receipt of the Decision and Order or, if a timely request for rehearing was made, within 30 days of the receipt of the rehearing decision.