STATE OF MICHIGAN
STATE OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
FOR THE DEPARTMENT OF COMMUNITY HEALTH
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IN THE MATTER OF:

[redacted],

Docket No. 2013-50383 PHR
Case No. 37761885

Appellant
_____/

DECISION AND ORDER

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

After due notice, a hearing was held [redacted]. [redacted], the Appellant, appeared on her own behalf. [redacted], Clinical Pharmacist for [redacted] ("MMA"), represented the Department of Community Health.

ISSUE

Did the Department properly deny the Appellant's request for prior authorization for Provigil (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. The Appellant is a [redacted] year old Medicaid recipient. (Exhibit 1, page 10)

2. On or about [redacted], the Department received a prior authorization request from the Appellant's physician for the medication Provigil for a diagnosis of organic hypersomnia, unspecified. (Exhibit 1, page 10)

3. On or about [redacted], MMA requested a copy of the sleep study and for any treatments tried previously to be noted if applicable. (Exhibit 1, page 5)

4. On or about [redacted], the Department received a prior authorization request from the Appellant's physician for the medication Provigil for a diagnosis of hypersomnia. The physician indicated that the Appellant had a sleep study that showed lack of REM sleep and did not show sleep apnea. (Exhibit 1, pages 4-6)

5. The Michigan Medicaid Guidelines state that Provigil may be approved for the following diagnoses: narcolepsy, fatigue associated with multiple

sclerosis, obstructive sleep apnea and (OSA)/obstructive sleep apnea syndrome (OSAS), and myotonic dystrophy. For shift-work sleep disorder, Michigan Department of Community Health (MDCH) review is required. (Exhibit 1, page 13)

6. The request was forwarded to a MDCH physician reviewer. On [redacted], the MDCH reviewer denied the request because there was no approvable diagnosis. (Exhibit 1, page 7)

7. On [redacted], an Adequate Action Notice was sent to the Appellant indicating the request for Modafinil was denied. (Exhibit 1, page 9)

8. On [redacted], the Appellant's Request for Hearing was received by the Michigan Administrative Hearing System. (Exhibit 1, page 2)

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

(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 provides, in pertinent part, as follows regarding prior authorizations:

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.

Medicaid Provider Manual; Pharmacy Section
Version Date: April 1, 2013, Pages 14-16

The Department is authorized by federal law to develop a formulary of approved prescriptions and a prior-authorization process. In this case, the Michigan Department of Community Health PDL & MAP criteria for Provigil (Modafinil) and Nuvigil (Armodafinil) states:

Diagnosis to approve:

1. **Narcolepsy**: PDL criteria applies; trial on preferred CNS stimulant required (see "starred" medications in PDL chart under ADD/ADHD criteria)
2. **Fatigue associated with multiple sclerosis**
3. **Obstructive sleep apnea (OSA) / Obstructive sleep apnea syndrome (OSAS):** confirmed by a sleep study. C-PAP therapy, if appropriate for the patient, must be noted as having been maximized. Note if there have been any other medication failures.
4. **Myotonic dystrophy (for Provigil**® only)
5. **Shift-work sleep disorder:** all requests will require MDCH review and must contain information regarding the following:
   - Have opportunities for maximizing sleep been addressed with the patient?
   - Has obtaining enough sleep been emphasized with the patient?

- Has the patient been counseled regarding appropriate sleep hygiene? Please document.
- Is the patient able to adjust work hours?
- Does the patient's shift vacillate between overnight hours and daytime hours?
- Is the patient currently taking sedating medications and, if so, for what diagnosis?
- What specific effects, other than "feeling sleepy" or "fatigue", is the patient experiencing?

Refill tolerance for Narcolepsy medications (HIC3 = H8Q)

- The narcolepsy (HIC3 = H8Q) refill tolerance for lock-in patients (LOC = 13 or LOC = 14) will be 95% effective 1-3-12.
- The 75% usage will also remain in effect for the rest of the population.

Requests for controlled substances must be under the name and ID of the prescribing physician, not the NP or PA.

Michigan Medicaid Clinical and PDL Criteria,
Provigil ® (Modafinil) and Nuvigil ® (Armodafinil),
May 1, 2013, page 200 (emphasis in original).
(Exhibit 1, page 13)

The prior authorization request indicates that Provigil was requested to treat the diagnosis of hypersomnia. The physician indicated that the Appellant had a sleep study that showed lack of REM sleep and did not show sleep apnea. (Exhibit 1, pages 4 and 6) The Clinical Pharmacist explained that the prior authorization request and information provided was reviewed under the criteria set forth above. MMA could not authorize the request because there was no documentation of an approvable diagnosis. (Clinical Pharmacist Testimony) The MDCH physician reviewer also denied the request noting no approvable diagnosis. (Exhibit 1, page 7) Therefore, denial notices were issued to the Appellant and the prescribing physician. (Exhibit 1, pages 8-9)

The Appellant disagrees with the denial and testified her sleep study showed she does not get any REM sleep. The Appellant gets 10-16 hours of sleep per day, but still has excessive daytime sleepiness. The Appellant falls asleep during the day. (Appellant Testimony)

The Department's denial was proper based upon the limited information received with this prior authorization request. The [redacted] prior authorization requests did not list an approvable diagnosis within the Department's criteria. (Exhibit 1, pages 4, 10, and 13) Accordingly, the Department's determination to deny the Appellant's prior authorization request for Provigil must be upheld.

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 based on the information submitted for the [redacted] prior authorization requests.

IT IS THEREFORE ORDERED that:

The Department's decision is AFFIRMED.

\s_____
Colleen Lack
Administrative Law Judge
for James K. Haveman, Director
Michigan Department of Community Health

Date Signed: August 13, 2013

Date Mailed: August 13, 2013

[redacted]

cc: [redacted]

***** NOTICE *****

The Michigan Administrative Hearing System 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 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.