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

Docket No. 2011-11490 PHR
Case No. 83847774

[redacted]

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], appeared the Appellant's behalf. [redacted] represented the Department of Community Health.

ISSUE

Did the Department properly deny the Appellant'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. The Appellant is [redacted] Medicaid recipient.

2. On [redacted], the Department received a prior authorization request from the Appellant's psychiatrist for the medication Provigil for bipolar disorder. (Exhibit 1, page 3)

3. The Michigan Medicaid Guidelines state that Provigil may be approved for the following diagnoses: narcolepsy, fatigue associated with multiple sclerosis, and obstructive sleep apnea (OSA)/Obstructive sleep apnea syndrome (OSAS). (Exhibit 1, page 8)

4. The Department faxed the Appellant's psychiatrist a request for additional information. Four questions were listed on the fax. (Exhibit 1, pages 3-4)

5. The psychiatrist's office responded by fax, but did not provide additional information in response to all of the questions. The response did not list any additional providers involved in therapy for this diagnosis, only the requesting

psychiatrist. It also indicated that the Appellant was on Provigil 200 mg, ½ tab daily for excessive daytime sleepiness with major depression and now his dose needs to be increased to 200 mg once daily. (Exhibit 1, page 4)

6. The request was forwarded to a Department physician reviewer. The Department reviewer denied the request because there was no approvable diagnosis. (Exhibit 1, page 5)

7. On [redacted], an Adequate Action Notice of denial was sent to the Appellant. (Exhibit 1, page 7)

8. A request for a formal, administrative hearing was received on [redacted]. (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, 2010, 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 and Nuvigil states:

Diagnosis to approve:

1. **Narcolepsy**: Diagnosis MUST be confirmed by a sleep study. A copy of the PSG (polysonography)/MSLT (multiple sleep latency test) with findings **MUST** be faxed to us to confirm the diagnosis specifically as narcolepsy. Sleep study findings/impressions, etc that do not specifically identify an absolute diagnosis of narcolepsy should be forwarded to a cliical pharmacist for MDCH review.
   The **Epworth Sleepiness Scale (ESS)** is not an unacceptable sleep study exam. It is a self administered test to determine excessive daytime sleepiness, and is **not** an acceptable test per our criteria to establish and confirm the diagnosis of narcolepsy.

   PDL criteria apply (see preferred list under ADD/ADHD criteria- must have trial on preferred ADHD medication), Technicians should check with a clinical pharmacist if unsure of PDL issue.

2. **Fatigue associated with Multiple Sclerosis.**

3. **Obstructibe sleep apnea (OSA) / Obstructive sleep apnea syndrome (OSAS);** confirmed by a sleep study. We must have a copy of the 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. **Requests for controlled substances must be under the name and ID of the prescribing physician, not the NP or PA.**

Michigan Department of Community Health (MDCH) PDL & MAP Criteria, Provigil ® (Modafinil) and Nuvigil ® (Armodafinil), November 15, 2010, page 174 (emphasis in original). (Exhibit 1, page 8)

The Department reviewed the prior authorization request and information provided against the criteria set forth above. It was determined that the information provided was not sufficient to meet the criteria. There were no records indicating an approvable diagnosis. Therefore, a denial notice was mailed to the Appellant.

The Appellant's [redacted] provided testimony that the Appellant has been on this medication for a little over five years, which had been covered by private insurance until the end of [redacted]. The PA was sought because the Appellant was approved for Medicaid coverage effective [redacted]. Her testimony also indicated that the Appellant does have other doctors treating him and there are additional diagnoses. She testified that the Appellant had a sleep study in [redacted].

The Department's denial was proper based upon the limited information received with this prior authorization request. The Appellant is free to re-submit the request for prior authorization at any time. He may wish to have a different provider submit the prior authorization request who has access to the needed information and documentation to support the prior authorization criteria.

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.

Colleen Lack
Administrative Law Judge
for Olga Dazzo, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 3/9/2011

***** NOTICE *****

The State Office of Administrative Hearings and Rules 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 State Office of Administrative Hearings and Rules 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.