STATE OF MICHIGAN
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
P.O. Box 30763, Lansing, MI 48909
(517) 335-2484; Fax: (517) 373-4147

IN THE MATTER OF:

[redacted]

Docket No. 15-008113 PHR
Case No. [redacted]

Appellant
[redacted]/

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and MCL 400.37, and upon Appellant's request for a hearing.

After due notice, a hearing was held on July 22, 2015. Appellant appeared and testified on her own behalf. [redacted], a Clinical Pharmacist with Magellan Medicaid Administration (MMA), represented the Michigan Department of Health and Human Services (DHHS or Department).

ISSUE

Did the Department properly deny Appellant's prior authorization request for the medication Nuvigil?

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] beneficiary who has been diagnosed with Idiopathic Hypersomnia. (Exhibit A, page 4).

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

3. On [redacted], MMA received a prior authorization request submitted on Appellant's behalf by a [redacted] and requesting Nuvigil 250 mg for Appellant. (Exhibit A, page 4; Testimony of [redacted]

4. In that request, Appellant's doctor identified Appellant's diagnosis of idiopathic hypersomnia; stated that the Appellant and her doctor have tried other stimulant medications without success; and indicated that the Nuvigil appears to have been effective in reducing Appellant's sleepiness over the past four months. (Exhibit A, page 4; Testimony of [redacted]

5. MMA and a physician with the Department both reviewed that request and each determined that it should be denied as Medicaid does not cover Nuvigil for

[1] The Notice of Hearing in this matter identified Appellant's last name as "[redacted] However, during the hearing, Appellant confirmed that her last name is "[redacted]

treatment of idiopathic hypersomnia. (Exhibit A, pages 4-6; Testimony of [redacted]

6. [redacted] MMA sent notice of the denial to Dr. Boss. (Exhibit A, page 7).

7. On [redacted], MMA sent written notice to Appellant that the request was denied. (Exhibit A, page 8).

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

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), 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 10-11

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 Appellant's.

Here, the Michigan Medicaid Clinical and PDL Criteria developed and used by the Department with respect to Nuvigil requires, among other criteria, that:

> **Diagnosis for approve**:
>
> 1. **Narcolepsy:** PDL criteria applies; trial on preferred CNS stimulant required (see medications below 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 diagnoses?
>   - What specific effects, other than "feeling sleepy" or "fatigue", is the patient experiencing?

MMA and the Department denied the prior authorization request submitted on Appellant's behalf pursuant to the above policies. Specifically, both MMA and the Department's physician reviewer found that the request for Nuvigil in this case was based on a diagnosis of idiopathic hypersomnia and that Appellant's diagnosis is not one of the listed diagnoses for which Nuvigil can be approved.

In response, Appellant testified that she has worked with her doctor on alternative treatments or medications in the past, but those attempts were unsuccessful and that Nuvigil has been the only medication that has helped her. She also testified that the Nuvigil has been life-changing for her. Appellant further argued that drugs are often discovered to have benefits unrelated to their initial purpose, she feels Nuvigil is one of those cases, and that she believes it will eventually be approved for treatment of idiopathic hypersomnia.

Appellant bears the burden of proving by a preponderance of the evidence that the Department erred in denying her prior authorization request.

Given the record in this case, Appellant has failed to meet that burden of proof and the Department's decision must therefore be affirmed. While the undersigned Administrative Law Judge sympathizes with Appellant and she may very well be correct that Nuvigil will one day be approved to treat her condition, he has no authority to override the current policy that applies this case, which specifically limits Medicaid coverage to certain diagnoses. Appellant's undisputed diagnosis in this case is not a diagnosis on the required diagnoses list and, consequently, the Department's denial was proper based on the submitted information.

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 Appellant's prior authorization request.

IT IS THEREFORE ORDERED that:

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

Steven Kibit

Steven Kibit
Administrative Law Judge
for Nick Lyon, Director
Michigan Department of Health and Human Services

Date Signed: [redacted]

Date Mailed: [redacted]

[redacted]

[redacted]

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cc: [redacted]

***** NOTICE *****

The Michigan Administrative Hearing System 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 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 60 days of the mailing date of the Decision and Order or, if a timely request for rehearing was made, within 60 days of the mailing date of the rehearing decision.