RICK SNYDER
GOVERNOR

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

SHELLY EDGERTON
DIRECTOR

[redacted]

Date Mailed: March 24, 2016
MAHS Docket No.: 16-015548
Agency No.: [redacted]
Petitioner: [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, and two adjournments, a telephone hearing was held on March 15, 2017. Attorney [redacted] appeared on Petitioner's behalf. [redacted], a Clinical Pharmacist with [redacted] (MMA), appeared and testified on behalf of the Michigan Department of Health and Human Services (DHHS or Department).

ISSUE

Did Respondent properly deny Petitioner'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. MMA contracts with the Department to review prior authorization requests for specified medications. (Testimony of Respondent's representative).

2. On September 29, 2016, MMA received a prior authorization request submitted on Petitioner's behalf by a [redacted] that requested the medication [redacted] for Petitioner. (Exhibit A, pages 9-10).

3. In the request to MMA, [redacted] identified Petitioner as having a diagnosis of chronic fatigue, unspecific. (Exhibit A, page 9).

4. During its review, MMA determined that the prior authorization request could not be approved because Petitioner's diagnosis was not on the list of diagnoses for which the requested medication can be approved. (Exhibit A, page 8; Testimony of Respondent's representative).

5. MMA therefore forwarded Petitioner's request to the Department, whose physician reviewer also found that MMA must: "deny, no approvable diagnosis". (Exhibit A, page 11).

6. MMA then sent Petitioner's doctor an electronic notice of denial. (Exhibit A, page 12).

7. On October 1, 2016, it also sent a written notice of denial to Petitioner. (Exhibit A, page 13).

8. On October 28, 2016, the Michigan Administrative Hearing System (MAHS) received the request for hearing filed in this matter regarding that denial. (Exhibit A, pages 3-7).

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 15-17

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 has done so and has identified specific diagnoses for which Nuvigil may be approved: Narcolepsy; Fatigue associated with multiple sclerosis;

Obstructive sleep apnea or Obstructive sleep apnea syndrome; Myotonic dystrophy; and Shift-work sleep disorder. *See* Exhibit A, page 14.

In this case, Respondent denied Petitioner's prior authorization request pursuant to the above criteria. Specifically, its representative testified that request was denied after a review by a Department physician because Petitioner's chronic fatigue is not on the list of diagnoses for which the requested medication can be approved.

Petitioner's representative disagrees with the denial, but she does not dispute the above facts relied upon by Respondent or the diagnosis identified by her physician. Instead, Petitioner's representative asserted that Petitioner received the requested medication through her Medicaid coverage in the State of Colorado for six years and that there are no other medications that have been able to assist Petitioner. She also asked about other avenues for getting the medication approved and noted that Petitioner is currently in the process of acquiring more clinical information.

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

Given the record and applicable criteria in this case, Petitioner has failed to meet that burden of proof. MMA 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 approve the request given Petitioner's diagnosis. It also forwarded the request to a Department physician reviewer who concurred with the denial. Petitioner may disagree with the applicable criteria, but the undersigned Administrative Law Judge is bound by it and what Petitioner received in another state is not relevant here. Respondent's decision must therefore be affirmed.

DECISION AND ORDER

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

IT IS, THEREFORE, ORDERED that:

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

Steven

SK/tm

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

Counsel for Petitioner

[redacted]

[redacted]

[redacted]

[redacted]