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

IN THE MATTER OF:

[redacted],

Docket No. 2013-15815 PHR
Case No. [redacted]

Appellant
_____/

DECISION AND ORDER

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

After due notice, a hearing was held [redacted]. [redacted], Appellant's [redacted] appeared and testified on Appellant's behalf. [redacted], a Pharmacist with the Magellan Medicaid Administration ("Magellan"), represented the Michigan Department of Community Health ('MDCH" or "Department").

ISSUE

Did the Department properly deny Appellant's prior authorization request for the drug Modafinil/Provigil?

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] year-old male who has been diagnosed with Schizophrenia Paranoid Type; Major Depressive Disorder, Recurrent; Generalized Anxiety Disorder; and Mild Mental Retardation. (Respondent's Exhibit A, pages 3, 7).

2. In [redacted] Magellan received a prior authorization request for Modafinil for Appellant from [redacted], Appellant's primary care physician. (Respondent's Exhibit A, pages 5-6).

3. However, per the Michigan Medicaid Clinical and PDL Criteria, Modafinil may only be approved to treat certain diagnoses, none of which Appellant has. (Respondent's Exhibit A, page 15).

4. Given that Appellant did not have one of the diagnoses identified in policy, Appellant's prior authorization request was sent to the Department for a physician review. (Uncontested testimony at hearing).

5. Following the physician review, Appellant was approved for Modafinil for 90 days, or the time period between [redacted] and [redacted]. (Respondent's Exhibit A, page 8).

6. The approval notice for the request also stated that Appellant's doctor was to submit the results of the use of Modafinil with the next prior authorization request. (Respondent's Exhibit A, page 8).

7. Appellant was prescribed and used Modafinil for approximately 90 days following the approval. (Uncontested testimony at hearing).

8. On [redacted], [redacted] submitted a prior authorization request for a continuation of Modafinil. (Respondent's Exhibit A, page 7).

9. However, no results of the previous use of the drug were submitted along with that request. (Respondent's Exhibit A, page 7).

10. Given that Appellant did not have one of the diagnoses identified in the applicable policy; the prior authorization request was again sent to the Department for a physician review. (Respondent's Exhibit A, page 6).

11. The physician reviewer subsequently determined that the request did not meet the criteria for approval. (Respondent's Exhibit A, pages 13).

12. Specifically, in the Notice of Prior Authorization Determination dated [redacted], the MDCH physician wrote:

> Modafinil Deny. MDCH approval was granted in [redacted] for [redacted] months only. Specific results of use on a [redacted] month basis was not submitted as requested. For any consideration of continuance this information must be provided. [Respondent's Exhibit A, page 13.]

13. On [redacted], Magellan also sent written notice to Appellant that the Prior Authorization request was denied because it did not meet criteria. (Respondent's Exhibit A, pages 4, 14).

14. On [redacted], the Michigan Administrative Hearing System (MAHS) received a request for hearing filed by Appellant. (Respondent's Exhibit A, 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 –
>
> 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.
>
> C. 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:
>
> D. Agents when used for anorexia, weight loss, or weight gain.

E. Agents when used to promote fertility.

F. Agents when used for cosmetic purposes or hair growth.

G. Agents when used for the symptomatic relief of cough and colds.

H. Agents when used to promote smoking cessation.

I. Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

J. Nonprescription drugs.

K. 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.

L. Barbiturates.

M. Benzodiazepines.

N. 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.

* * *

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.

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).

The Department is therefore authorized by federal law to develop a formulary of approved prescriptions and a Prior Authorization process. In this case, the Michigan Medicaid program guidelines list criteria for Modafinil that provide that the drug may only been approved if certain diagnoses are present. Those diagnoses are narcolepsy; fatigue associated with multiple sclerosis; obstructive sleep apnea (OSA)/obstructive sleep apnea syndrome (OSAS); myotonic dystrophy; and shift-work sleep disorder.

It is undisputed that Appellant has not been diagnosed with any of the above conditions and, therefore, Magellan correctly determined that the information provided was not sufficient to meet the criteria after reviewing the prior authorization request.

Consequently, MDCH review was required before approval could be granted and Appellant's prior authorization request was sent to the Department for a physician review. However, as discussed above, while the Department approved a prior request, it also specifically stated that any future approval or continuation was contingent on the results of the earlier use of the drug and that those results must be provided along with the request. Here, the results were not submitted and, like Magellan, the physician reviewer also determined that the Appellant does not meet the criteria for approval.

Appellant's representative disagrees with the denial, but she acknowledges that Appellant's doctor failed to provide any results of the earlier use of the drug. She also testified that she and Appellant have no control over what the doctor sends in.

While this Administrative Law Judge is sympathetic to the fact that Appellant cannot control what his doctor submits, the Department and Magellan can only make their decision in light of the information they do have. Here, the denial was proper based upon the information received with the prior authorization request. If Appellant is able to get provide additional information in the future, he can always resubmit his request.

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.

[redacted]
Docket No. 2013-15815 PHR
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IT IS THEREFORE ORDERED that:

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

/s/

Steven Kibit
Administrative Law Judge
for James K. Haveman, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: February 25, 2013

***** 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.