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:

Docket No. 14-010998 PHR

[redacted], [redacted] [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 on [redacted]. [redacted] appeared and testified on Appellant's behalf. Appellant also testified on his own behalf. [redacted] a Clinical Pharmacist with [redacted] ([redacted]"), represented the Michigan Department of Community Health ("MDCH" or "Department").

ISSUE

Did the Department properly deny Appellant's prior authorization request for Oxycodone 30 mg tablets?

FINDINGS OF FACT

The Administrative Law Judge, based upon the competent, material and substantial evidence on the whole record, finds as material fact:

1. [redacted] contracts with the Department to review drug prior authorization requests. (Testimony of [redacted]).

2. Appellant is a [redacted] year-old Medicaid beneficiary who has been diagnosed with a degenerative lumbar/lumbosacral disc; carpal tunnel syndrome; cervical spondylosis without myelopathy; discogenic syndrome; lumbar spinal stenosis with neurogenic claudication; and lumbosacral spondylosis without myelopathy . (Respondent's Exhibit A, pages 3, 19).

3. On or about [redacted] received a prior authorization request submitted on Appellant's behalf by a [redacted] and requesting Oxycodone 30 mg tablets for Appellant. (Respondent's Exhibit A, page 25; Testimony of [redacted].

4. On that form, [redacted] also indicated that Appellant can use a preferred medication and that no previous medications had been tried. (Respondent's Exhibit A, page 25).

5. MMA reviewed that request and sent a notice of denial to [redacted]. (Respondent's Exhibit A, page 26).

6. Regarding the reason for the denial, the notice indicated that Oxycodone is not a preferred medication and that, in order for it to be approved, a failed trial of [redacted] preferred medications is required. (Respondent's Exhibit A, page 26).

7. The notice also directed [redacted] to consider the use of preferred medications; document a clinical reason why the preferred medications are inappropriate; or document the preferred medications that have been tried and that failed. (Respondent's Exhibit A, page 26).

8. On [redacted] resubmitted the prior authorization request and the Appellant's claims history demonstrated that a trial of [redacted] preferred medications had been conducted. (Testimony of [redacted]).

9. [redacted] then forwarded Appellant's prior authorization request to the Department for a physician review. (Respondent's Exhibit A, page 29; Testimony of [redacted].

10. Following that review, the physician for the Department's physician found that the request should be denied at that time and asked that [redacted] "provide explanation for high daily dose – consider evaluation by pain specialist". (Respondent's Exhibit A, page 29).

11. On [redacted], the Department sent Appellant's physician written notice of the denial and the information requested by the Department's physician. (Respondent's Exhibit A, page 30).

12. On [redacted], the Department sent Appellant written notice that the prior authorization request was being denied on the basis that the request did not meet criteria. (Respondent's Exhibit A, page 31).

13. On [redacted], the Michigan Administrative Hearing System (MAHS) received the request for hearing in this matter. (Respondent's Exhibit A, pages 2-23).

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:

> 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).

The Department is therefore authorized by federal law to develop a formulary of approved prescriptions and a prior authorization process.

Here, with respect to Oxycodone 30 mg tablets, the Michigan Medicaid Clinical and PDL Criteria developed and used by the Department provides both that there must be a failure to respond to a therapeutic trial of two of the preferred medications before the Oxycodone can be approved and that, even if that criteria is met, the request must be reviewed by the MDCH:

> Is there a reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include:
>
> - Allergy to preferred medications
> - Contraindication to preferred medications

- A significant drug to drug interaction
- History of unacceptable side effects

Has there been a failure to respond to a therapeutic trial of one week of <u>two</u> of the preferred medications? If yes, allow the prior authorized medication. Document the details.

* * *

<u>Medication Specific Information to Aid in The Final Decision:</u>

* * *

3.**Oxycodone 20mg tabs, Oxycodone 30mg tabs, Oxycodone 20mg/ml conc soln, Meperidine 100mg tabs:** MDCH review will be required (even if PDL criteria is met) if a covered short acting narcotic analgesic cannot be used.

Respondent's Exhibit A, page 32

Moreover, with respect to prior authorization requests and drugs, the applicable version of the Medicaid Provider Manual (MPM) states:

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.

* * *

8.6 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.

MPM, July 1, 2014 version
Pharmacy Chapter, pages 14, 16

Here, [redacted] and the Department reviewed the prior-authorization request against the criteria and policy set forth above. It was determined that the prior authorization request should be denied because, while the specific PDL criteria was met, the Department's reviewing physician found that such a high daily dose was not medically necessary. The Department's physician and [redacted] also asked Appellant's doctor to provide an explanation for the high daily dose or to consider an evaluation by a pain specialist, but no further information was received.

Appellant challenges that decision on appeal and, in doing so, bears the burden of proving by a preponderance of the evidence that [redacted] and the Department erred in denying her request. Moreover, the undersigned Administrative Law Judge's jurisdiction is limited to reviewing the denial in light of the information available at the time that decision was made.

Given the record in this case and the applicable policies, Appellant has failed to meet her burden of proof and the denial must be affirmed. The criteria identified above for the requested drug requires both that the request be reviewed by the MDCH and that the drug be medically necessary. However, in this case, when the request was reviewed by a MDCH physician, she determined that the request must be denied as such a high daily dose was not medically necessary given the available evidence.

In response, Appellant testified that she was following her doctor's recommendations and that she requires the medication due to her severe pain resulting from significant injuries. However, Appellant's broad statements regarding her need for this particular medication at the requested dosage are unsupported and the prescribing physician did not submit the additional information or details requested by the Department.

To the extent Appellant has new or updated information to provide, she and her doctor can submit a new prior authorization request. With respect to the previous denial at issue in this case, however, the undersigned Administrative Law Judge finds that the Department's denial is proper based on the submitted information and lack of medical necessity.

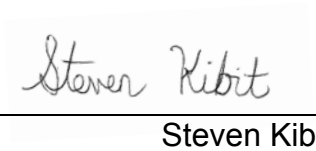
DECISION AND ORDER

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 for Oxycodone 30 mg tablets.

[redacted]
Docket No. 14-010998 PHR
Decision and Order

IT IS THEREFORE ORDERED that:

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



Steven Kibit
Administrative Law Judge
for Nick Lyon, Director
Michigan Department of Community Health

Date Signed: [redacted]

Date Mailed: [redacted]

SK/db

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.