STATE OF MICHIGAN
STATE OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
FOR THE DEPARTMENT OF COMMUNITY HEALTH
P.O. Box 30763, Lansing, MI 48909
(877) 833-0870; Fax: (517) 334-9505

IN THE MATTER OF:

[redacted]

Docket No. 2011-1016 PHR
Case No. 92547089

Appellant

_____/

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and 42 CFR 431.200 *et seq.,* following the Appellant's request for a hearing.

After due notice, a hearing was held on [redacted]. [redacted] appeared on her own behalf. [redacted], represented the Michigan Department of Community Health (MDCH).

ISSUE

Did the Department properly deny the Appellant's request for prior authorization of Suboxone?

FINDINGS OF FACT

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

1. The Appellant is a Medicaid recipient.

2. On [redacted], the Appellant sought prior authorization for continued use of Suboxone. (Exhibit 1, page 4)

3. Medicaid guidelines state that Suboxone may only be approved for 12 months, unless certain criteria are met. Further, all requests for continued use must be forwarded to a Department physician reviewer. (Exhibit 1, pages 23-24)

4. The Appellant has been on Suboxone/Subutex since [redacted]. (Exhibit 1, pages 21-22; Testimony of Gerhart)

5. With the request, the Appellant's physician provided the following information: that the Appellant was no longer in counseling because she had completed the program in [redacted] and that tapering her from Suboxone was not appropriate. (Exhibit 1, pages 11, 17)

6. The request and supporting information were forwarded to a physician reviewer. The physician reviewer denied the request for the following reasons: the Appellant was not in counseling, the drug screen was over one month old, and there was no plan for tapering the medication. (Exhibit 1, pages 13-14)

7. An Adequate Action Notice of denial was sent to the Appellant on [redacted]. (Exhibit 1, page 15)

8. In response to the denial notice, the Appellant's physician again requested Suboxone for the Appellant and advised the Department that the Appellant had scheduled an appointment to resume counseling and that she had a negative drug screen in [redacted]. (Exhibit 1, pages16-18)

9. Based on the new information received from the Appellant's physician, the Department approved continued use of Suboxone for the Appellant for one month, noting that any future requests should either include a tapering plan or an acknowledgement of the time-limited coverage by Medicaid and a plan of care after termination of coverage. (Exhibit 1, pages 16, 19-20)

10. The Appellant requested a formal, administrative hearing on [redacted]. (Exhibit 1, pages 2-6)

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.

(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).

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 addresses prior-authorization requirements as follows:

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.

MDCH Medicaid Provider Manual; Pharmacy Section
Version Date: July 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, MDCH's PDL & MAP criteria only supports use of Suboxone for a maximum period of 12 months, including weaning. MDCH does not support long-term use of Suboxone. However, the Department's witness testified that extensions beyond 12 months can be granted at the Department's discretion. (Exhibit 1, pages 23-24; Testimony of [redacted]). The Department requires that the following information be provided in order to consider an extension:

1. Details of attendance and progress in a formal counseling program.
2. Details of plan for continued therapy.
3. Details that the beneficiary is not using illicit drugs and any documentation supporting the clinical basis for that certification (drug screen must be at minimum test for opiods and hydrocodone).
4. If the formal treatment is from another provider, the information must originate from the **treatment program physician of record.**

(Exhibit 1, page 24)

In addition, the PDL & MAP criteria notes that any request for use beyond 12 months should address "issues of length of therapy and long-term plan for the individual recipient." (Exhibit 1, page 24)

The Department reviewed the prior-authorization request and information submitted against the criteria set forth above. It determined that the information did not support an extension in this case. More specifically, there was no tapering plan submitted to the Department.

The Appellant testified that she is not ready to go off the Suboxone. She stated that she recently had a baby and is suffering from post-partum depression. She further stated that she also recently had a relapse because of severe tooth pain. She is fearful of a relapse if the Suboxone is not continued.

This Administrative Law Judge has reviewed the evidence of record. While I sympathize with the Appellant's position in wanting to continue taking a medication that is working for her, the information submitted to the Department did not support granting an extension beyond the original 12 months of use. Accordingly, the Department's denial is proper based on the evidence in the record. However, the Appellant's physician may resubmit the request for prior authorization at any time.

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.

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Kristin M. Heyse
Administrative Law Judge
for Janet Olszewski, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 1/4/2011

***** 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.