STATE OF MICHIGAN
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
P.O. Box 30763, Lansing, MI 48909
(877) 833-0870; Fax: (517) 373-4147

IN THE MATTER OF:

Docket No. 15-016050 PHR

[redacted]

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 Appellant's request for a hearing.

After due notice, a hearing was held on [redacted]. Appellant appeared on her own behalf. [redacted], Therapist, appeared as a witness. [redacted], Clinical Pharmacist for [redacted], represented the Michigan Department of Health and Human Services (MDHHS or Department).

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. Appellant is a [redacted] year old Medicaid beneficiary, born [redacted]. (Exhibit A, p 3; Testimony)

2. On [redacted] Appellant's physician sought prior authorization for treatment with Suboxone. (Exhibit A, p 6; Testimony)

3. Appellant's claim history shows paid claims for Suboxone each month from [redacted] through [redacted] and from [redacted] through [redacted], for a total of [redacted] paid claims for Suboxone. (Exhibit A, pp 16-18; Testimony)

4. Medicaid guidelines only support intervention with Suboxone for a maximum duration of [redacted] months to include weaning. Requests for continued use must be forwarded to a Department physician reviewer and may still qualify if there

are extenuating circumstances. Additional documentation is required for renewal requests beyond [redacted] consecutive months. (Exhibit A, pp 22-26; Testimony)

5. On [redacted], additional information was requested from the prescribing physician describing and documenting extenuating circumstances that may allow for therapy exceeding [redacted] months. It was also noted that additional information would be needed, specifically: details regarding compliance with counseling and prescriber appointments, a detailed taper plan, and a recent drug screen along with a completed Suboxone fax form. (Exhibit A, p 4; Testimony)

6. On [redacted] [redacted] and [redacted], additional information was received from Appellant's doctor and therapist. (Exhibit A, pp 8-15; Testimony)

7. The requests and supporting information were forwarded to a physician reviewer. The physician reviewer denied the request stating, "Deny-has almost [redacted] years of therapy supported by the state and remains on Suboxone. Please refer to chronic intervention." (Exhibit A, pp 19-20; Testimony)

8. An Adequate Action Notice of denial was sent to the Appellant on [redacted]. (Exhibit A, p 21; Testimony)

9. Appellant requested a formal, administrative hearing on [redacted]. (Exhibit 1)

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.

Medicaid Provider Manual
Pharmacy Section
April 1, 2015, pp 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 support use of Suboxone for a maximum period of [redacted] months, including weaning. MDCH does not support long-term use of Suboxone. However, the Department's witness testified that extensions beyond [redacted] months can be granted at the Department's discretion. (Exhibit 1, pages 18-21; Clinical Pharmacist Testimony). The Department requires that the prescriber provide the following information in order to consider an extension:

- The information requested for initial approval.
- Information on compliance/non-compliance with counseling sessions.
- Information on compliance/non-compliance with the prescribing physician,
- The plan for continued therapy to include a tapering schedule.
- Documentation that the patient is not using illicit drugs; including a copy of the drug screen no more than one month old.
- Details regarding extenuating circumstances warranting continued coverage,
- Result of the referral to the substance abuse treatment center for chronic intervention (see details under section marked "General MDCH information about coverage"

- A screen-print of paid claims through POS claims history.

(Exhibit A, page 19)

First, it should be noted that Appellant's request for an administrative hearing was untimely, so jurisdiction for a Medicaid fair hearing is lacking. The Social Security Act and the federal regulations which implement the Social Security Act require an opportunity for fair hearing to any recipient who believes the Department may have taken an action erroneously. *See 42 CFR 431.200 et seq.* The opportunity to fair hearing is limited by a requirement that the request be made within 90 days of the negative action. The regulations provide, in pertinent part:

> Request for hearing.
>
> (d) The agency must allow the applicant or recipient a reasonable time, not to exceed 90 days from the date that notice of action is mailed, to request a hearing. *42 CFR 431.221(d).*

Here, an Adequate Action Notice of denial was sent to the Appellant on [redacted] but Appellant's request for hearing was not received by the Michigan Administrative Hearing System until [redacted], beyond the [redacted] day deadline. As such, Appellant's request was untimely and should be dismissed.

However, even if Appellant's appeal was considered, her request would still be denied because the Department reviewed the prior-authorization requests against the criteria set forth above and determined that the information did not support an extension in this case.

The Department's clinical pharmacist testified that on [redacted], Appellant's physician sought prior authorization for treatment with Suboxone. The Department's clinical pharmacist indicated that, upon review, Appellant's claim history showed paid claims for Suboxone each month from [redacted] through [redacted] and from J[redacted] through [redacted], for a total of [redacted]6 paid claims for Suboxone. The Department's clinical pharmacist testified that because Appellant had already received more than [redacted] months of Suboxone, additional information was requested from the prescribing physician describing and documenting extenuating circumstances that might allow for therapy exceeding [redacted] months. It was also noted that additional information would be needed, specifically: details regarding compliance with counseling and prescriber appointments, a detailed taper plan, and a recent drug screen along with a completed Suboxone fax form. The Department's clinical pharmacist indicated that on [redacted], [redacted] and [redacted], additional information was received from Appellant's doctor and therapist and that the requests and supporting information were forwarded to a physician reviewer. The physician reviewer denied the request stating, "Deny-has almost [redacted] years of therapy supported by the state and remains on Suboxone. Please refer to chronic intervention."

Appellant testified she has been paying out of pocket for Suboxone and it is very difficult as she also has two children to support. Appellant indicated that she had a relapse after her first trial of Suboxone, but is doing better now as she is in therapy and a treatment program. Appellant indicated that she has tried other programs and detox, but they did not work for her. Appellant indicated that she was trying to do whatever she can to get clean.

Appellant's therapist testified that she assisted Appellant in her request for an appeal and authored the letter found on page 9 of Exhibit A. Appellant's therapist indicated that Appellant was not in counseling the first time she tried Suboxone, so that probably led to her relapse. Appellant's therapist testified that Appellant is now doing well, has been attending all of her appointments, and has not had any positive drug screens. Appellant's therapist indicated that Appellant is not a candidate for Methadone therapy because she cannot get to the treatment center every day. Appellant's therapist indicated that she believes Appellant will be able to begin tapering off Suboxone in [redacted] to [redacted] months.

This Administrative Law Judge has reviewed the evidence of record. First, Appellant's appeal is untimely and should be dismissed due to lack of jurisdiction. Second, even if Appellant's case was considered fully, Appellant submitted additional information to support her claim, but the review was still denied by the State's reviewing physician, who indicated: "Deny-has almost [redacted] years of therapy supported by the state and remains on Suboxone. Please refer to chronic intervention." Based on the evidence presented, Appellant has not been referred to chronic intervention. Accordingly, the Department's denial is proper based on the submitted information.

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.

Robert J. Meade
Administrative Law Judge
for Nick Lyon, Director
Michigan Department of
Health and Human Services

Date Signed: [redacted]

Date Mailed: [redacted]

RJM/db

cc: [redacted]

***** NOTICE *****

The Michigan Administrative Hearing System for the Department of Health and Human Services 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 for the Department of Health and Human Services 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.