

**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. 15-000954 PHR

██████████

██████████

██████████

Appellant

_____ /

DECISION AND ORDER

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

After due notice, a hearing was held on ██████████ Appellant's mother, appeared and testified on Appellant's behalf. ██████████ a Clinical Pharmacist with ██████████"), represented the Michigan Department of Community Health ("MDCH" or "Department").

ISSUE

Did the Department properly deny Appellant's prior authorization requests for the drug Suboxone?

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 drug prior authorization requests. (Testimony of ██████████)
2. Appellant is a ██████ year-old Medicaid beneficiary. (Exhibit A, page 7).
3. On ██████████, ██████ received a prior authorization request submitted on Appellant's behalf by a ██████████ and requesting the drug Suboxone (Buprenorphine-Naloxone) for Appellant. (Exhibit A, pages 3-4; Testimony of ██████████).
4. At that time, ██████████ indicated that the Suboxone would be used to treat Appellant's pain and opioid dependence, and that Appellant was not enrolled in any substance abuse counseling. (Exhibit A, pages 3-4; Testimony of ██████████).

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5. [REDACTED] reviewed that request and determined that it should be denied as MDCH does not cover Suboxone for the dual-diagnosis of pain and opioid dependence. (Exhibit A, pages 3-5; Testimony of [REDACTED].
6. On [REDACTED] sent notice of the denial to [REDACTED] (Exhibit A, page 7). [REDACTED] also sent written notice of the denial to Appellant on [REDACTED] (Exhibit A, page 9).
7. On [REDACTED], the day after he received notice of the denial, Dr. [REDACTED] resubmitted the prior authorization request, stating that he was no longer treating Appellant for pain management, just opioid dependence, and that he was counseling Appellant. (Exhibit A, pages 3-4; Testimony of [REDACTED].
8. [REDACTED] reviewed the new request and determined that it should be denied as the required substance abuse counseling must be provided by a certified addiction specialist and, while a licensed physician, [REDACTED] is not a certified addiction specialist. (Exhibit A, pages 3-4, 6; Testimony of [REDACTED] i).
9. [REDACTED] then sent notice of the denial to both [REDACTED] and Appellant. (Exhibit A, pages 8, 10).
10. On [REDACTED], the Michigan Administrative Hearing System ("MAHS") received the request for hearing in this matter. (Exhibit 1, pages 1-2).

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), 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).

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- (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.

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- (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

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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

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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, the Michigan Medicaid Clinical and PDL Criteria developed and used by the Department with respect to Suboxone requires, among other criteria, that:

Diagnosis for approval: Confirmation of a diagnosis of opioid dependence that does not include pain management.

* * *

6. Patient is undergoing active, formal substance abuse counseling.
 - If the prescribing physician (physician making the request) is a psychiatrist or certified addiction specialist, we need to document whether or not he/she is rendering the counseling.
 - If the prescribing physician (physician making the request) is not a psychiatrist or certified addiction specialist, we need to document the following:
 - i. Full name of the psychiatrist or certified addiction specialist. If neither is known then we can use the pending counseling appointment date.
 - ii. Name of the program or agency

Exhibit A, pages 11, 14

Given the above criteria, ██████████ and the Department properly denied the prior authorization requests submitted on the minor Appellant's behalf.

In the first request, ██████████ indicated that the Suboxone would be used to treat Appellant's pain and opioid dependence, and that Appellant was not enrolled in any substance abuse counseling. However, the approved diagnosis for Suboxone coverage is opioid dependence that does not include pain management. Moreover, Appellant must be undergoing active, formal substance abuse counseling in order for the drug to be approved.

In the second request, submitted the day after he received notice that the first request was denied, ██████████ now indicated that he is no longer treating Appellant for pain

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management, just opioid dependence, and that he was counseling Appellant. However, [REDACTED] did not explain the discrepancies between the two prior authorization requests. Moreover, even if [REDACTED] was only treating Appellant for opioid dependence and was providing counseling himself, the above policy requires that the counseling be provided by a psychiatrist or certified addiction specialist and [REDACTED] is neither. As noted by the Department's witness, the mere fact that [REDACTED] is a licensed physician and can prescribe Suboxone does not qualify him as a certified addiction specialist.

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 requests.

IT IS THEREFORE ORDERED that:

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

Steven Kibit

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.