STATE OF MICHIGAN
STATE OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
FOR THE DEPARTMENT OF COMMUNITY HEALTH
P.O. Box 30763, Lansing, MI 48909
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IN THE MATTER OF:

Docket No. 2013-27242 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 the Appellant's request for a hearing.

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

ISSUE

Did the Department properly deny the Appellant's request for prior authorization of [redacted]?

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 or about [redacted], the Appellant sought prior authorization for treatment with [redacted]. (Exhibit 1, pages 7-8)

3. The Appellant's claim history shows paid claims for [redacted] each month from [redacted] through [redacted] (Exhibit 1, page 11)

4. Medicaid guidelines only support intervention with [redacted] for a maximal duration of [redacted] months to include weaning. Requests for renewal requests for interrupted/restart therapy must be forwarded to a Department physician reviewer. (Exhibit 1, pages 18-22)

5. On or about [redacted], additional information was requested from the prescribing physician to clarify counseling information and requesting the date of the [redacted] review. (Exhibit 1, pages 1 and 9)

6. The prior authorization request and related information were forwarded to a physician reviewer. The physician reviewer denied the request because it was incomplete, noting the date of the recent [redacted] review and evidence the patient is not currently using illicit drugs (recent urine drug screen) were needed. (Exhibit 1, page 12)

7. On or about [redacted], a Notice of Prior Authorization Determination was sent to the prescribing physician indicating a denial due to incomplete information. The notice indicated the date of the most recent [redacted] review and evidence the patient is not currently using illicit drugs were needed. (Exhibit 1, pages 6 and 13)

8. On or about [redacted], the prescribing physician faxed the form requesting additional information back to the Department with some counseling information but wrote "yes" rather than a date for the [redacted] review. A letter was also provided form the physician. (Exhibit 1, pages 1 and 9-10)

9. On [redacted], an Adequate Action Notice was sent to the Appellant indicating the prior authorization request was denied because he did not meet the criteria. (Exhibit 1, page 14)

10. The prior authorization request and related information were forwarded to a physician reviewer a second time. The physician reviewer denied the request because there was still no urine drug screen and it was not clear if the request was for maintenance [redacted] to prevent a relapse, which is not covered. (Exhibit 1, page 15)

11. On or about [redacted], a Notice of Prior Authorization Determination was sent to the prescribing physician indicating the request was denied based on criteria not being met noting there was still no urine drug screen and it was not clear if the request was for maintenance [redacted] to prevent a relapse, which is not covered. (Exhibit 1, page 16)

12. On [redacted], an Adequate Action Notice of denial was sent to the Appellant indicating the prior authorization request was denied because he did not meet the criteria. (Exhibit 1, page 17)

13. On [redacted], the Michigan Administrative Hearing System received the Appellant's Request for Hearing. (Exhibit 1, pages 2-3)

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.

8.5 ADDITIONAL DOCUMENTATION

Depending on the specific drug being prescribed, additional medical documentation 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: January 1, 2013, Pages 14-16

The Department is authorized by federal law to develop a formulary of approved prescriptions and a prior authorization process. MDCH's PDL & [redacted] criteria only support use of [redacted] for a maximum period of [redacted] months, including weaning. MDCH does not support long-term use of [redacted] (Exhibit 1, page 18) In this case, the Appellant Appellant's claim history shows paid claims for [redacted] each month from [redacted] through [redacted]. (Exhibit 1, page 11) Therefore, this was a request to re-start [redacted] after a [redacted] month gap from the prior [redacted] months of treatment.

The policy requires MDCH review for renewal requests for interrupted/restart therapy:

> **RENEWAL REQUESTS- INTERRUPTED/RESTART THERAPY:**
>
> MDCH review is required. All of the following are required for MDCH physician review:
>
> - The information requested for initial approval.
> - Some reference to the reason(s) for lapse in therapy.
> - A screen-print of paid claims through POS claims history.
>
> (Exhibit 1, page 22)

The information required for an initial request includes counseling information as well as the provider having registered with [redacted] and checked the [redacted] report within the las[redacted] days. (Exhibit 1, page 21)

The Department reviewed the prior-authorization request and additional information against the criteria set forth above. It was determined that the available information did not support an approval in this case. Some counseling information was provided in response to the request for additional information, but no date of the [redacted] review was provided by the prescriber. Further, the prescriber indicated he was afraid the Appellant is going to go back into opiate addiction again, therefore he is recommending [redacted] a day for at least one year. (Exhibit 1, page 9-10) The Department's physician review noted that it was not clear if the request was for maintenance [redacted]e to prevent a relapse, which is not covered. (Exhibit 1, page 15)

The Appellant disagrees with the denial and testified that he did well on a similar protocol in the past, but only had coverage for so long. The Appellant believes he has met the criteria and this would improve his quality of life. As a stipulation of his lease, the Appellant is subject to random urine screens. The Appellant has had clean urine drug screens. Further, the Appellant has signed releases for the Department to get information needed, be it counseling, urine drug screens, or other needed information. The Appellant is on a fixed income and the medication is expensive, though there are some generics now. (Appellant Testimony)

[redacted]
Decision and Order

This Administrative Law Judge has reviewed the evidence of record. The Appellant's desire to go back to a treatment that previously worked for him is understandable. However, the policy specifically only supports the use of [redacted] for a maximum period of [redacted] months, including weaning and MDCH does not support long-term use of [redacted]. (Exhibit 1, page 18) The Appellant previously received [redacted] months o [redacted] from [redacted] through [redacted]. (Exhibit 1, page 11) While the Appellant testified he has had clean urine screens, other required information was not provided. Specifically, the date of the required [redacted] review was not provided, despite the request for additional information. Further, based on the letter from the physician, it appears this is a request for maintenance [redacted] to prevent a relapse, which is not covered. (Exhibit 1, page 10) Accordingly, the Department's denial was proper based on the available 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.

/s/
Colleen Lack
Administrative Law Judge
for James K. Haveman, Director
Michigan Department of Community Health

Date Signed: [redacted]

Date Mailed: [redacted]

CL/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 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.