STATE OF MICHIGAN
STATE OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
FOR THE DEPARTMENT OF COMMUNITY HEALTH
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IN THE MATTER OF:

[redacted]

Appellant
_____/

Docket No. 2009-19218 PHR
Case No. [redacted]

DECISION AND ORDER

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

After due notice, a telephone hearing was held [redacted]. [redacted] (the Appellant) appeared and testified on his own behalf. [redacted], [redacted] [redacted], represented [redacted], the Department of Community Health's Pharmacy Benefits Manager (hereinafter, "the Department").

ISSUE

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

FINDINGS OF FACT

Based upon the competent, material and substantial evidence presented, I find, as material fact:

1. Appellant is not a Medicaid beneficiary. He is an Adult Benefits Waiver participant. As such, he has pharmacy benefits.

2. On [redacted] the Department received a request from the Appellant's family practitioner for approval of coverage of the product Xyrem to treat the Narcolepsy the Appellant suffers.

3. There is uncontested medical evidence of the narcolepsy diagnosis in the record.

4. The Department sought additional medical information before authorization was approved. Specifically, the Department sought information pertaining to the Appellant's diagnosis of "intractable depression" and efforts to address his mental health issues.

5. The medical evidence in the record indicates the Appellant is taking Cymbalta. Additionally, the record indicates the Appellant is/was seeking electro shock treatments for his depression. No additional information pertaining to mental health treatment is in evidence.

6. A second request for Xyrem was made [redacted].

7. The Department denied the Appellant's request for Xyrem on [redacted].

8. The Appellant appealed the denial, and filed his request for hearing on [redacted].

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.

> Sec. 1927(d) [of the Social Security Act] [*42 USC 1396r-8(d)*]
> -- 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.

(4) REQUIREMENTS FOR FORMULARIES—

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) of this section.

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

The Department may not approve an outpatient drug when the prescribed use is not approved by federal law or if the use of the medication is not supported by one or more approved compendia described in federal law.

SECTION 6 – GENERAL NONCOVERED SERVICES

This section specifies general coverage restrictions. However, drugs in other classes may not be covered. Pharmacies should review the MPPL for specific coverage. When possible, pharmacies are encouraged to suggest alternative covered therapy to the prescriber if a product is not covered.

The following drug categories are **not covered** as a benefit:

- Agents used for anorexia or weight loss.
- Agents used for weight gain.
- Agents used for cosmetic purposes or hair growth.
- Agents used for symptomatic relief of cough and colds.
- Experimental or investigational drugs.
- Agents used to promote fertility.

- Agents used to promote smoking cessation not on the MPPL.
- Vitamin/Mineral combinations not for prenatal care, end stage renal disease or pediatric fluoride supplementation.
- Covered outpatient drugs that the Labeler seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the Labeler or their designee.
- Covered outpatient drugs where the Labeler limits distribution.
- Proposed less-than-effective (LTE) drugs identified by the Drug Efficacy Study Implementation (DESI) program.
- Over-the-counter drugs not on the MPPL.
- Drugs of Labelers not participating in the Rebate Program.
- Drugs prescribed for "off label" use if there is no generally accepted medical indication in peer reviewed medical literature (Index Medicus), or listing of such use in standard pharmaceutical references such as Drug Facts and Comparisons, AMA Drug Evaluations, American Hospital Formulary Service Drug Information, or DRUGDEX Information Systems.)
- Drugs prescribed specifically for medical studies.
- Drugs recalled by Labelers.
- Drugs discontinued (past one year).
- Lifestyle agents.
- Standard Infant Formulas.
- Drugs used to treat gender identity conditions, such as hormone replacement.
- Drugs covered by the Medicare Part D benefit.
- Drugs not FDA approved or licensed for use in the United 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.

8.4 DOCUMENTATION REQUIREMENTS

For all requests for PA, the following documentation is required:

- Pharmacy name and phone number;
- Beneficiary diagnosis and medical reasons 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.

Michigan Department of Community Health
Medicaid Provider Manual-Pharmacy
Version Date: July 1, 2007; pages 12-16

The Department asserts the Appellant failed to provide all information sought pertaining to his mental health status. The Department's doctor apparently seeks an evaluation or assessment of his mental health status and treatment. This falls within the prior authorization parameters as set forth in the criteria detailed above. This ALJ has reviewed the evidence in the record. The Appellant's records do provide information pertaining to the Appellant's mental health treatment (Cymbalta); however, apparently, the MDCH reviewing physician is concerned with the Appellant's mental health status such that this information has been found insufficient. The Appellant has been asked for more specific information in accordance with the MDCH guidelines. Thus, if he is to pursue obtaining prior authorization for this medication, which is listed on the formulary but still subject to prior authorization requirements, he must comply with the Department's stated requirements.

The Appellant did not assert he had submitted a psychological assessment as per the MDCH physician. This undisputed fact will determine the outcome of the hearing. Because the denial was in accordance with the Medicaid Guidelines regarding prior authorization for

prescription drugs, I must find the Department's actions were proper in this case.

DECISION AND ORDER

Based on the above findings of fact and conclusions of law, I find the Department's denial of the Appellant's prior authorization request for Xyrem is appropriate.

IT IS THEREFORE ORDERED that:

The Department's decision is AFFIRMED.

Jennifer Isiogu
Administrative Law Judge
for Janet Olszewski, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 7/1/2009

***** NOTICE *****

The State Office of Administrative Hearings and Rules 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 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.