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]

Docket No. 2011-7629 PHR
Case No. 73261605

Appellant

_____/

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 hearing was held on [redacted]. [redacted] appeared on his own behalf. [redacted], represented the Department of Community Health.

ISSUE

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

FINDINGS OF FACT

The ALJ, based upon 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 Zolpidem, a sedative hypnotic. (Exhibit 1, page 4)

3. Medicaid guidelines state that a sedative hypnotic may only be approved for three months, unless certain criteria are met. (Exhibit 1, pages 9-13)

4. Since [redacted] several sedative hypnotic medications have been authorized for the Appellant. Recent authorizations were made for Zaleplon, from [redacted] and Zolpidem in [redacted]. (Exhibit 1, pages 3-5)

5. [redacted] was unable to approve the Appellant's prior authorization request without Department review because the Appellant had exceeded 102 days of therapy with the combination of previously approved medications in the therapeutic class and the request was not from a psychiatrist with a diagnosis of sleep disorder/insomnia secondary to a mental health diagnosis, or neurologist with a diagnosis of sleep disorder/insomnia secondary to any other diagnosis, or a specified or clearly related to mental retardation or cancer. (Exhibit 1, pages 3-5, 11-12, and [redacted] Testimony)

6. The Appellant's prior authorization request was forwarded to a Department physician reviewer. The Department reviewer denied the request because there was insufficient information supplied to explain the need for a nightly hypnotic, noting an evaluation for chronic sleep disorder was needed. (Exhibit 1, pages 7-8 and 11-12)

7. An Adequate Action Notice of denial was sent to the Appellant on [redacted]. (Exhibit 1, page 8)

8. The Appellant requested a formal, administrative hearing [redacted]. (Exhibit 1, page 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)*, 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

(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 provides, in pertinent part, as follows regarding prior authorizations:

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
Version Date: April 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, the Michigan Department of Community Health PDL & MAP criteria for a sedative hypnotic exceeding three months requires that attempts at weaning the beneficiary off the medication be made. In addition,

diagnosis and medical necessity information must be provided for sedative/hypnotic therapy exceeding 102 days. (Exhibit 1, pages 9-13) The clinical notes from [redacted] indicate that the [redacted], approval for Zaleplon was made following a total of 4 months of therapy with another medication. It was noted that there had not been any attempts to wean. The [redacted] Notice of Prior Authorization Determination indicates this was a three month approval to allow time for a deliberate attempt to wean from sedative hypnotic therapy and that all future requests would require Department physician review for extended therapy. Such a request could be made by phone or by fax, but should address all issues on the Medicaid fax form for extended sedative/hypnotic therapy. (Exhibit 1, page 4)

The Department reviewed the prior-authorization request and information supplied for the [redacted] prior approval request for Zolpidem against the criteria for sedative/hypnotic therapy exceeding 102 days. (Exhibit 1, pages 9-13) It was determined that the criteria had not been met, thus no approval was issued. Specifically, the Department [redacted] noted there was insufficient information to explain the need for a nightly hypnotic and an evaluation for chronic sleep disorder was needed. (Exhibit 1, pages 6-7) A denial notice was mailed to the Appellant. (Exhibit 1, page 8)

The Appellant disagrees with the denial, but acknowledged that he has tried several medications over the past 8 years. He testified that Ambien (Zolpidem) is the only one that has helped him. The Appellant also stated that he has not had any sleep studies or testing yet. He explained that he has asked to have this set up but his doctor has not followed through. The Appellant submitted a letter from his physician indicating he has sleep difficulties and co-morbidities. (Exhibit 2) However, this letter did not explain the need for a nightly hypnotic, no diagnosis was listed, no sleep studies or testing results were indicated, and the co-morbidities were not listed.

This ALJ has reviewed the evidence of record. While this ALJ sympathizes with the Appellant's position in wanting to continue taking a medication that is working for him, the criteria is clear that sedative hypnotics may only be authorized for more than three months when documentation of diagnosis and medical necessity have been provided. The needed diagnosis and medical necessity information was not provided with the prior authorization request. Additionally, the Appellant testified he has not undergone sleep studies or testing. Accordingly, the Department's denial is proper based on the evidence in the record. The Appellant's physician can always submit a new prior authorization request with supporting documentation.

DECISION AND ORDER

The ALJ, 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.

Colleen Lack
Administrative Law Judge
for Olga Dazzo, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 2/22/2011

***** 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.