STATE OF MICHIGAN
STATE OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
FOR THE DEPARTMENT OF COMMUNITY HEALTH
P.O. Box 30763, Lansing, MI 48909
(877) 833-0870; Fax: (517) 334-9505

IN THE MATTER OF:

[redacted],

Appellant

[redacted]/

Docket No. 2009-10607 PHR
Case No. [redacted]
Load No. [redacted]

DECISION AND ORDER

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

After due notice, a hearing was held on [redacted]. [redacted] appeared on behalf of the Appellant. She had no witnesses. [redacted], [redacted] represented the Department. She had no witnesses.

ISSUE

Did the Department properly deny Appellant's request for prior authorization (PA) of the brand name medication, Depakote?

FINDINGS OF FACT

The Administrative Law Judge, based upon the competent, material and substantial evidence on the whole record, finds as material fact:

1. At the time of hearing the Appellant is a [redacted]-year-old Medicaid beneficiary. (Appellant's Exhibit #1)

2. The Appellant is afflicted with seizure disorder and is developmentally delayed. (Appellant's Exhibit #1 and Department's Exhibit A, p. 4)

3. On [redacted], the Department received the faxed PA request for Depakote from [redacted], a neurologist on behalf of the Appellant. (Department's Exhibit A, pp. 1, 3, 4)

4. Absent evidence of a try-fail on generic Depakote the request was forwarded to Department physician [redacted], for review. (Department's Exhibit A, pp. 1, 3, 5)

5. [redacted] denied the request as there appeared to be sufficient supplies of the generic product available from the same manufacturer at an available pharmacy. (Department's Exhibit A, p. 5)

6. The Appellant was notified of the denial on [redacted] (Department Exhibit A, p.6)

7. The instant appeal was received by SOAHR on [redacted] (Appellant's 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.

Social Security Act § 1927(d), [*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.

(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

(3) [Omitted]

(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.
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> (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).
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Furthermore, the Medicaid Provider Manual (MPM) requires satisfaction of certain threshold criteria, documentation, prior approvals, and more before certain classes of drugs are authorized for filling of prescription:

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.

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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.

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. (Emphasis supplied)

MPM, §§8.2, 8.4, 8.6, Pharmacy, January 1, 2009, Pages 14, 15, 16.[1]

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The Department witness, [redacted], testified that the requesting physician failed to include clinical documentation on the trial-failure of generic Depakote and had instructed on PA request that the Appellant could use the same generic brand throughout the year – to enable monitoring through blood work. See Department's Exhibit A, at page 4. Coupled with [redacted] evaluation that sufficient numbers of generic products existed, Martini opined that the denial was appropriate – although she encouraged the Appellant to reapply if try-fail evidence existed for his preferred prescription medication.

The Appellant's representative testified that the generic brand last utilized caused a seizure in the Appellant - a process she did not want the Appellant to repeat. However, she admitted in her testimony that she was unaware of the try-fail requirement.

On review, the Department is fully within its right to require documentation of the try-fail requirement to obtain non-generic brand Depakote. Absent supporting clinical data the Appellant failed to preponderate his burden of proof and the Department's denial of PA was appropriate at the time it was made.

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 request for PA of non-generic Depakote.

IT IS THEREFORE ORDERED that:

The Department's decision is AFFIRMED.

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Dale Malewska
Administrative Law Judge
for Janet Olszewski, Director
Michigan Department of Community Health

1 The MPM edition cited here ([redacted] is identical to the edition in place at the time of the Department's action on [redacted]

cc: [redacted]

Date Mailed: 3/31/2009

***** 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.