

**STATE OF MICHIGAN  
MICHIGAN ADMINISTRATIVE HEARING SYSTEM  
FOR THE DEPARTMENT OF COMMUNITY HEALTH**

P.O. Box 30763, Lansing, MI 48909  
(877) 833-0870; Fax: (517) 373-4147

**IN THE MATTER OF:**

██████████,

Appellant

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**Docket No.** 2014-12466 PHR

**Case No.** 35172219

**DECISION AND ORDER**

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

After due notice, a hearing was held ██████████. Appellant appeared and testified on her own behalf.

██████████, a Clinical Pharmacist with the Magellan Medicaid Administration ("MMA"), represented the Michigan Department of Community Health ("MDCH" or "Department").

**ISSUE**

Did the Department properly deny Appellant's prior authorization request for the drugs voltaren gel and oxycontin?

**FINDINGS OF FACT**

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

1. Appellant is a ██████-year-old Medicaid beneficiary who has been diagnosed with antiphospholipid antibody syndrome, joint pain, oral ulcers, malar rash history. (Respondent's Exhibit A.3; B.3)
2. On ██████████, MMA received two prior authorization requests for voltaren gel and oxycotin for back pain for Appellant from Dr. Radden. (Respondent's Exhibit A.5; B)
3. In response to the prior authorization request, MMA sought additional information from Appellant's doctor regarding the request for volaren gel. No

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clinical reason was provided as to why the oral form of the product could not be used. (Respondent Exhibit A.1,4,6,7

4. On [REDACTED] MMA issued a denial notice denying the voltaren gel for the reason that no evidence was submitted to such that alternative oral trials were conducted (Respondent's Exhibit A.9-12).
5. On [REDACTED] MMA requested clarification from Appellant's doctor's office as to why Appellant cannot use a preferred medication, or, evidence of a trial of one week of two of the preferred medications. (Respondent's Exhibit B.1).
6. A review by MMA determined that Appellant's physician did not submit evidence of required trials for oxycotin.
7. On [REDACTED] MMA issued a denial notice denying the oxycotin on for the reason that the drug does not meet medical criteria. (Respondent's Exhibit B.11-17)
8. On [REDACTED], the Michigan Administrative Hearing System (MAHS) received a request for hearing in this matter. (Respondent's Exhibit B.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).
- (B) A state may exclude or otherwise restrict coverage of a covered outpatient drug if –

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- (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

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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

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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).

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The Department is therefore authorized by federal law to develop a formulary of approved prescriptions and a Prior Authorization process.

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, 2011, Pages 14-16*

The bottom line for both of these drugs in this case is the Department has certain financial arrangements with drug companies for financial discounts. Those drugs become preferred drugs. Use of drugs not on the preferred list require prior approval. The prior approval process criteria is listed in a document titled the Michigan Medicaid Clinical and PDL Criteria pursuant to the title of the document found in Respondent

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Exhibits A16-17 and B 12-13. On the bottom of each page are the words: "Proprietary & Confidential; Revised [REDACTED]." The Department Exhibits contain some of the pages out of a "347" page document. The MMA representative at the administrative hearing did not know where this criteria is published, but testified that it "is available to physicians." Based on some of the pages submitted in the Respondent's exhibits, it is a 347 page document as of the [REDACTED] revision date. (See Respondent Exhibit A.12)

Criteria for the voltaren gel drug is found on page 24 of 347. This criteria requires evidence of an allergy to preferred medications, or, a history of unacceptable side effects, or a "...therapeutic trial of one month of at least two preferred medications." (Respondent Exhibit A.12)

At this hearing, Appellant disputed the facts as to whether she met the criteria. However, unrefuted evidence on the record is that Appellant's physician did not submit evidence to show that Appellant met the criteria. (See Respondent Exhibit A.5-13)

As to the oxycotin, the criteria required is similar (See Exhibit B.16,17) As with the voltarin drug, Appellant once again disputed whether she met the criteria. However, once again, Appellant did not dispute that her physician did not submit the necessary documentation to show that she had met the criteria.

In neither case did Appellant have any contrary evidence to submit at the administrative hearing to support her position.

As to the law and policy, as noted above, the Social Security Act gives the Department the authority and right to engage in financial agreements with drug companies for cost saving purposes, and to establish criteria to require patients under these plans to show reasons for use of non-preferred drugs.

In this case, the administrative law judge has reviewed the prior authorization request and denials, and finds that they are in conformance with Department criteria and not contrary to law. As such, the denials must be upheld.

Appellant expressed an understanding at the administrative hearing as to what documentation would suffice to meet the Department criteria.

**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 request.

**IT IS THEREFORE ORDERED** that:

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

Janice Spodarek  
Administrative Law Judge  
for James K. Haveman, Director  
Michigan Department of Community Health

  
Date Signed: February 19, 2014

Date Mailed: February 19, 2014

cc: 

**\*\*\* 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.