STATE OF MICHIGAN
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
FOR THE DEPARTMENT OF COMMUNITY HEALTH
P.O. Box 30763, Lansing, MI 48909
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IN THE MATTER OF:

[redacted]

Docket No. 2014-34682 PHR
Case No. [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 Appellant's request for a hearing.

After due notice, a hearing was held on [redacted] Appellant's mother [redacted] appeared and testified on the Appellant's 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 Versed (Midazolam)?

FINDINGS OF FACT

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

1. Appellant is a [redacted] year old Medicaid beneficiary, born [redacted] (Exhibit A, pp. 5, 7 and testimony).

2. On [redacted], Appellant's physician [redacted] specializing in neurology, submitted a PA request for Versed (Midazolam) for a diagnosis of complex partial epilepsy to be dispensed in a nasal atomizer and given as a nasal spray. (Exhibit A, pp. 5-35 and testimony)

3. The requested medication is not on the Michigan formulary, and is not indicated for the diagnosis or route of administration requested. Thus, the request was for an "off label" use of a non-formulary product. (Exhibit A, p. 1 and testimony).

4. On [redacted], after clinical review of Appellant's PA request for Versed (Midazolam) was denied for not meeting criteria for authorization due to the fact that the request was for an "off label" use of a non-formulary product.

Appellant's request was then forwarded to MDCH and was reviewed by [redacted] a physician reviewer. On [redacted] concurred in the denial stating the request did not meet criteria, citing drug exclusion, i.e., drugs prescribed for "off label use are generally not covered". (Exhibit A, pp. 1, 4, 36, 37, 39-41 and testimony). No additional requests or information has been submitted by the prescriber. (Exhibit A, p. 1 and testimony).

5. An Adequate Action Notice of denial was sent to the Appellant on [redacted] (Exhibit A, pp. 3, 38).

6. Appellant requested a formal, administrative hearing on [redacted] (Exhibit A, pp. 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.

* * *

8.6 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*, January 1, 2014, pp 14-16].

The Pharmacy chapter in the Medicaid Provider Manual sets forth drug categories that are not covered as a benefit. Section 6 states in part:

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:

* * *

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. [Medicaid Provider Manual, Pharmacy, §6 - General Noncovered Services, April 1, 2014, p. 12].

The Michigan Medicaid Clinical and PDL Criteria for Non-Formulary Medications provides that if a non-formulary drug is not licensed for the requested diagnosis MDCH physician review is required. It further provides that a request for a non-formulary drug will be denied when there is a valid, identifiable formulary alternative drug. [Exhibit A, pp. 39-40]. The Department is authorized by federal law to develop a formulary of approved prescriptions and a prior authorization process.

The Department's clinical pharmacist [redacted] testified on [redacted] Appellant's physician [redacted] specializing in neurology, submitted a PA request for Versed (Midazolam) for a diagnosis of complex partial epilepsy to be dispensed in a nasal atomizer and given as a nasal spray. (Exhibit A, pp. 5-35 and testimony). [redacted] testified the requested medication is not on the Michigan formulary, and is not indicated for the diagnosis or route of administration requested. Thus, the request was for an "off label" use of a non-formulary product. (Exhibit A, p. 1 and testimony).

[redacted] testified on [redacted], after clinical review of Appellant's PA request for Versed (Midazolam) was denied for not meeting criteria for authorization due to the fact that the request was for an "off label" use of a non-formulary product. [redacted] testified Appellant's request was then forwarded to MDCH and was reviewed by [redacted] a physician reviewer. [redacted] testified on [redacted] concurred in the denial stating the request did not meet criteria, citing drug exclusion, i.e., drugs prescribed for "off label use are generally not covered". (Exhibit A, pp. 1, 4, 36, 37, 39-41 and testimony). [redacted] testified no additional requests or information has been submitted by the prescriber. (Exhibit A, p. 1 and testimony). [redacted] testified an Adequate Action Notice of denial was sent to the Appellant on [redacted].

Appellant's mother testified they have tried several medications for the Appellant and they have found that they need Versed to stop his petit mal seizures. Appellant's mother said when he has seizures he stops his respiration. If they do not have the Versed in a nasal atomizer they have to drill an IV into his bone in order to give him the medication to stop his seizures. Appellant's mother said it only makes sense to allow the use of the Versed as prescribed by the Appellant's doctor and thinks this case should be an exception. Appellant's mother said the Versed can save the Appellant's life and it is silly for the State not to cover it.

This Administrative Law Judge has reviewed the evidence of record. Here, Appellant's request was denied after a clinical review and it was then forwarded to MDCH and reviewed by [redacted], a physician reviewer, per Department policy. [redacted] upheld the previous denial for Versed (Midazolam). The undersigned has no authority to override the decision of the physician reviewer since that decision was made within policy. Policy requires that requests for an "off label" use of a non-formulary product, in this case Versed (Midazolam), must be reviewed by the Department and that was done in this case. The approval criteria states that drugs prescribed for "off label use are generally not covered". Accordingly, the Department's denial is proper based on the submitted 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**.

William D Bond

William D. Bond
Administrative Law Judge
for James K. Haveman, Director
Michigan Department of Community Health

Date Signed: [redacted]

Date Mailed: [redacted]

WDB/db

cc: [redacted]

***** NOTICE *****

The Michigan Administrative Hearing System 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 Michigan Administrative Hearing System 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.