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) 334-9505

IN THE MATTER OF:

[redacted],

Docket No. 2012-30815 PHR
Case No. [redacted]

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.,* upon the Appellant's request for a hearing.

After due notice, a hearing was held [redacted]. The Appellant was represented by his mother, [redacted].

[redacted], Clinical Pharmacist for [redacted], represented the Department of Community Health.

ISSUE

Did the Department properly deny the Appellant's request for coverage of the Daytrana patch?

FINDINGS OF FACT

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

1. The Appellant is a [redacted] Medicaid recipient.

2. On or about [redacted], the Department received a prior authorization request for the medication Daytrana (a patch) from the Appellant's general practitioner. (Exhibit A)

3. The Appellant's family practice physician prescribed the Daytrana patch and submitted the request for prior authorization. The doctor submitted a diagnosis of ADHD in the request for prior authorization.

4. Additional information provided by the provider includes the following: the Appellant has tired and failed Ritalin 5mg and Amphetamine 5ml. On the

prior authorization request the stated reason for requesting the exception is "has been using Daytrana successfully since [redacted]."

5. The Appellant had a prescription for the same medication filled in [redacted].

6. The requested medication is not covered unless approved by MDCH physical review because of coverage limitations.

7. Request for prior authorization was submitted to a MDCH physician reviewer because it did not meet Michigan Medicaid guidelines for approval.

8. The MDCH physician reviewed denied the request after requesting additional information. The additional information requested was "please provide an explanation for need for Daytrana versus another medication and please review MAPS as there is a question whether this child is receiving this medication at all."

9. The information submitted back to the doctor was that the Appellant had trialed Ritalin and Amphetamine and that his father will not administrator the medication to him when he stays with him. Additionally, the Appellant's mother stated the doctor told her to use a ½ patch, in explanation for why a refill had been requested sooner.

10. The MDCH physical reviewed again read the request for authorization and indicated she wanted information about the doses of failed medication, trial dates and reason for failure of each medication. She had already been provided information about the doses and dates of the medications on the prior authorization requests. The reason for failure for each medication was indicated as "not effective."

11. The MDCH denied the request for coverage of the medication after 2 reviews of the request and provision of the requested information.

12. Notice of denial was sent [redacted].

13. The Appellant requested a formal, administrative hearing [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.

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. The Department is also authorized by federal law to develop a prior authorization process. The Department's witness from First Health testified at hearing that the Daytrana patch is subject to prior authorization. Michigan Medicaid covers an oral dosage form of Daytrana/Methylphenidate. In order to be approved for the patch or non-oral dosage form of this medication, the provider must provide a reason for not using an oral dosage such as: patient is unable to take by mouth, OR patient's refusal/inability to swallow oral dosage forms even though they can swallow foods (…check claims history); OR provider to provide documented non-compliance with another long-acting methylphenidate ADHD med.

The Department's agent reviewed the prior authorization request and information provided against the criteria set forth above. It was determined that the information provided was not sufficient to meet the criteria. It was sent to MDCH for review, where the Department's physician reviewer denied the request after determining the criteria had not been satisfied with the information provided.

The Department acted in accordance with its policy in denying Appellant's request for the Daytrana patch. The preponderance of evidence on the record fails to establish that the Appellant is unable or refuses to take oral medications, and it is medically necessary for him to have this patch. Although the Department's other inquiries appear to be specifically addressed, there is no evidence addressing the reason for a patch rather than an oral dose. As stated above in the Medicaid Provider Manual, the Department may deny prior authorization if required documentation is not provided. Accordingly, the Department's denial is upheld.

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.

_____

Jennifer Isiogu
Administrative Law Judge
for Olga Dazzo, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: _____June 5, 2012_____

***** 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.