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:

Docket No. 2010-44021 PHR
[redacted], 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]. [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?

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 Medicaid recipient.

2. The Appellant sought prior approval for the medication Daytrana. It is for the diagnosis of ADHD.

3. The request was forwarded to a Department physician reviewer. The Department reviewer determined there was no documentation the Appellant had an inability to swallow oral medication, thus denied the request.

4. The Appellant's physician had noted on the request for prior authorization that the medication requested is the medication that works for him and he has taken it for 2 years.

5. An Adequate Action Notice of denial was sent to the Appellant [redacted].

6. 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.

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).

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 addresses Prior Authorization requirements below:

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.

8.3 RESPONSIBILITY FOR OBTAINING AUTHORIZATION

8.3.A. PHARMACY RESPONSIBILITY

Pharmacies may call the PBM Technical Call Center for exceptions on:

- Quantity;
- Early refills; and
- 72-hour supply of medication for emergency needs only when the prescriber is not available to obtain PA.

Pharmacies may call the PBM Clinical Call Center for exceptions on payment for brand name over the MAC.

The PBM Technical Call Center is available 24 hours per day/seven days a week.

Refer to the Directory Appendix for PBM's Call Center contact information.

8.3.B. PRESCRIBER RESPONSIBILITY

Prescribers or their designees may call the PBM Clinical Call Center for any PA, but must call for any request that falls outside the categories noted above as applying to pharmacies.

The PBM Clinical Call Center is available after hours by telephone and by pager. The PBM may also be contacted by fax or in writing via U.S. mail.

Refer to the Directory Appendix for the PBM Clinical Call Center contact information, PA contact information and hours of operation.

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.

8.5 ADDITIONAL DOCUMENTATION

Depending on the specific drug being prescribed, additional medical documentation may be required. The most common categories requiring additional documentation are:

8.5.A. BRAND OVERRIDE

Provide documentation of the therapeutic trial and failure reasons of the generic.

8.5.B. WEIGHT LOSS

- Current medical status, including nutritional or dietetic assessment.
- Current therapy for all medical conditions, including obesity.
- Documentation of specific treatments, including medications.
- Current accurate Body Mass Index (BMI), height, and weight measurements.
- Confirmation that there are no medical contraindications to reversible lipase inhibitor use; no malabsorption syndromes, cholestasis, pregnancy and/or lactation.
- Details of previous weight loss attempts and clinical reason for failure (at least two failed, physician supervised, attempts are 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: July 1, 2009, Pages 14-16

The Department is authorized by federal law to develop a formulary of approved prescriptions and a prior authorization process. *MDCH Medicaid Provider Manual,*

Pharmacy Section, July 1, 2009, pages 14 – 16. The Department may subject the request for covered medications to the prior authorization process. In this case, the Michigan Department of Community Health PDL & MAP criteria for the medication requested explicitly states the provider must list a reason for not using an oral dosage form of methylphenidate and lists examples:

> Patient is unable to take by mouth, OR
> Patient's refusal/inability to swallow oral dosage forms even though they can swallow foods (endorsed by P&T Comm, psychiatrist, but check claims history), OR
> Provider to provide documented non-compliance with another long-acting methylphenidate ADHD me (Concerta, Metadate CD/ER, Ritalin LA/SR) Standard CNS stimulant diagnosis criteria (ADHD/ADD; Daytrana is not approved for narcolepsy) and age limits for diagnosis of ADHD/ADD.

The Department reviewed the prior authorization request and documentation submitted against the criteria set forth above. It was determined the criteria had not been met, thus no approval was issued. A denial notice was mailed to the Appellant.

The Appellant provided testimony that he prefers the patch medication because he has tried the oral medications and they make his stomach hurt. This resulted in school absences. He stated the patch does not make him sick, that is why he prefers it. He was asked if he had trouble swallowing oral medications and answered no. He stated he would sometimes forget to take his medication, however. No other material evidence was presented.

This ALJ has reviewed the evidence of record. While this ALJ has sympathy for the Appellant's position in wanting to keep taking a medication that is working for him, the criteria is clear and does require his doctor to submit documentation that there is a reason why he is unable to take oral medication. There was no evidence submitted from the Appellant's doctor that he is unable to take the oral dose of medication. The prior authorization process and criteria set forth are allowable under the Policy. The Department's denial is proper based upon the evidence in the record. The Appellant is free to re-submit the request for prior authorization at any time.

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 Janet Olszewski, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 8/30/2010

***** 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.