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. 2011-27404 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]. [redacted], mother and Guardian, appeared the Appellant's behalf. [redacted] for [redacted] represented the Department of Community Health.

ISSUE

Did the Department properly deny the Appellant's request for prior authorization for Lupron Depot?

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] year old Medicaid recipient. (Exhibit 1, pages 8 and 14)

2. On [redacted], the Department received a prior authorization request from the Appellant's psychiatrist for the medication Lupron Depot listing diagnoses of pelvic pain, endometriosis and dysmenorrhea. (Exhibit 1, pages 8 and 14)

3. The Michigan Medicaid Guidelines state that Lupron Depot may be approved for diagnoses of endometriosis, prostate cancer, or precocious puberty. They also set out the critical information for office/clinic administration or home administration. For home administration, documentation is required with the prescriber's signature stating that the patient or another person not affiliated with the physician's office administering the medication to the patient has been instructed in the proper storage, handling, and administration of the medication. (Exhibit 1, page 23)

4. On [redacted], the prior authorization request was returned for additional information about where the injections is being administered, and if administered at home, it was noted that documentation is required with the prescriber's signature stating that the patient or another person not affiliated with the physician's office administering the medication to the patient has been instructed in the proper storage, handling, and administration of the medication. (Exhibit 1, pages 16-17 and 19)

5. On [redacted], the pharmacy was also advised that a signed statement from the prescriber is required stating that someone other than an agent of the doctor's office has been trained in the dosage, handling, and administration of the product. (Exhibit 1, page 16)

6. On [redacted], the Appellant's doctor was on the phone and stated that the Appellant's mother would be giving the injection. The prior authorization request was forwarded to see if the physician's statement was acceptable. (Exhibit 1, page 13)

7. On [redacted], the prior authorization request was denied because there was insufficient information why this can not be given in a doctor's office. (Exhibit 1, pages 20-21)

8. On [redacted], an Adequate Action Notice of denial was sent to the Appellant stating the reason for the action was it does not meet criteria. (Exhibit 1, page 22)

9. A request for a formal, administrative hearing was received on [redacted]. (Exhibit 1, pages 2-12)

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. In this case, the Michigan Department of Community Health PDL & MAP criteria for Luprolide Acetate Injection states:

Diagnosis to approve:

1. Endometriosis
2. Prostate Cancer
3. Precocious puberty

Critical Information:

- **Office/clinic administration (all products):**
  1. A **date-of-service** prior authorization for a POS/pharmacy claim for an approvable diagnosis billed through us for office administration may be entered **for the purpose of instructing the patient or another person administering the medication to the patient, such as a family member, in the proper storage, handling, and administration of the medication outside of the office/clinic setting.**
  2. A **date-of-service** prior authorization for a POS/pharmacy claim for copay billed through us for office administration may be entered applying regular copay requirements.
  3. Any other POS/pharmacy claim, regardless of diagnosis, billed through us for office administrations would not be approved. The claim should be treated as a technical denial using the Informational PA. The technical denial can be entered by a technician or a pharmacist. Informational PAS are not billed to the client. The provider can be directed to the **Provider Billing Assistance Helpline at 800-292-2550** if they need help in billing procedure and coding. Only in **extreme** circumstances would we forward a request to MDCH for physician review. It is not uncommon for an office to state that they do not follow this policy of office procurement and billing because of the financial costs involved. This does not qualify as an extreme circumstance! Technicians should forward any questionable issues to a pharmacist.

- **Home administration (Lupron Depot®** and **Lupron Depot-Ped®** only):
  Medicaid will allow us to enter a prior authorization for non-office/clinic administration of either of these two products for an approvable diagnosis as noted above as long as we have documentation (prescriber's signature is required) stating that the patient or another person administering this medication to the patient has been instructed in the proper storage, handling, and administration of the medication. A request for any diagnosis not listed above will require MDCH physician review, regardless of office/home/instruction issue.

Michigan Department of Community Health (MDCH) PDL & MAP Criteria, Leuprolide Acetate Injection, April 1, 2011, page 125 (emphasis in original). (Exhibit 1, page 23)

An approvable diagnosis was listed on the prior authorization request form, endometriosis. (Exhibit 1, pages 8 and 14) The Appellant's mother provided credible testimony that they were given different responses to what was still needed as they tried to obtain the prior authorization for this medication. The March 8, 2011, PA clinical notes indicate there were conflicting notes about where the medication would be administered, the doctor's office or the Appellant's home. (Exhibit 1, page 16-17) On March 8, 2011, the prior authorization request was returned for additional information, specifically:

> Is the injection being administered in the physician's office or in the patient's home?
>
> If the injection is being administered in the physician's office, your office would need to obtain the medication and bill for the medication as part of the office procedure.
>
> For home administration of the Lupron injection, we need the following information on file. The previous authorization does not have this information.
>
> If the injection is being administered in the patient's home, we must have documentation (prescriber's signature is required) stating that the patient or another person not affiliated with the physician's office administering the medication to the patient has been instructed in the proper storage, handling, and administration of the medication.
>
> (Exhibit 1, page 19)

During a [redacted], phone call with the Appellant's mother, it was noted that the Appellant's physician had contacted Medicaid but prior approval was not authorized. The Appellant's mother was told she should have the doctor or the pharmacy call to specify where the medication would be administered. It is noted that if it was to be given in the home, the medication should be approved. (Exhibit 1, page 16) The Appellant's doctor called on [redacted], and stated the Appellant's mother would be giving the injection. Despite not obtaining documentation signed by the prescriber, the request was forwarded to see if an exception could be made. (Exhibit 1, page 15)

The Department physician reviewer determined that the medication should be denied because there was insufficient information as to why this can not be given in a doctor's office noting that the medication is typically administered in the office setting. (Exhibit 1, page 20) However, the request for additional information sent to the Appellant's doctor only asked where the injection was going to be given, and for the required statement signed by the prescriber if the medication was to be administered at home. (Exhibit 1, page 19) The evidence does not indicate that the Appellant's doctor was ever asked to provide information explaining why the medication could not be given in the doctor's office.
The policy is clear that documentation with the prescriber's signature is required stating that the patient or another person not affiliated with the physician's office administering the medication to the patient has been instructed in the proper storage, handling, and

administration of the medication. The physician was notified of the requirement in the [redacted], request for additional information. (Exhibit 1, page 19) The evidence indicates that Appellant's doctor only called and gave a verbal statement that the Appellant's mother would be administering the medication. The Department's denial was proper because there was no documentation with the prescriber's signature stating that the Appellant's mother has been instructed in the proper storage, handling, and administration of the medication.

If she has not already done so, the Appellant may 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.

Colleen Lack
Administrative Law Judge
for Olga Dazzo, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 7/6/2011

***** 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.