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],

Appellant

Docket No. 2011-35767 PHR
Case No. [redacted]

/

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], RN, Clinical Liaison appeared on the Appellant's behalf. [redacted], mother, appeared as a witness for the Appellant. [redacted], Clinical Pharmacist for [redacted] represented the Department of Community Health.

ISSUE

Did the Department properly process the Appellant's [redacted], request for prior authorization for Genotropin?

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 4 year old Medicaid recipient. (Exhibit 1, page 22)

2. On [redacted], the Department received a prior authorization request for Genotropin from the Appellant's pediatric endocrinologist. The diagnosis for use of the medication indicated SGA, Intrauterine growth failure, and pancreatic insufficiency. (Exhibit 1, page 22)

3. Michigan Medicaid program guidelines allow for approval of growth hormone replacement therapy if there has been a diagnosis of 253.2 panhypopituitarism, 253.3 pituitary dwarfism, 259.8 endocrine disorders, 758.6 gonadal dysgenesis, 759.81 Prader-Willi Syndrome, or chronic kidney disease (CRF & ESRD). For a diagnosis of 783.4 lack of expected normal

physiological development delayed milestone; failure to gain weight; failure to thrive; lack of growth; physical retardation; short stature or any other diagnosis MDCH physician review is required. (Exhibit 1, page 28)

4. On [redacted], [redacted] faxed the Appellant's doctor a Notice of Prior Authorization Determination indicating "N/A" as the prior authorization status noting the request was previously denied on [redacted], with comments from the reviewing physician indicating there was insufficient information, specifically requesting clarification of the diagnosis in light of the lab results and a comment in a [redacted] note. (Exhibit 1, page 23)

5. No Adequate Action Notice was sent o the Appellant regarding the [redacted] prior authorization request.

6. [redacted] did not send the [redacted], prior authorization request for physician review because the information requested by the physician reviewer in a previous prior authorization denial for Genotropin for the Appellant had not been addressed. (Exhibit 1, page 1A and Clinical Pharmacist Testimony)

7. The Appellant's doctor provided additional information regarding the Appellant's diagnosis on the [redacted], prior authorization request form compared to the information submitted with the [redacted] prior authorization request. (Exhibit 1, pages 1-16 and 22)

8. On [redacted], correspondence requesting a hearing on the Appellant's behalf was received with the Appellant's mother's signature. Additional medical documentation was attached.

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, 2011, 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 Human Growth Hormone Replacement Therapy states:

Diagnosis to approve (ICD-9 Codes):

1. **253.2*:** Panhypopituitarism – Cachexia, pituitary; Necrosis of pituitary (postpartum); Pituitary insufficiency NOS; Sheehan's syndrome; Simmond's disease.
2. **253.3*:** Pituitary dwarfism – Isolated deficiency of (human) growth hormone [HGH]; Lorain-Levi dwarfism).
3. **259.8:** Endocrine disorders, nec – Other specified endocrine disorders: Pineal gland dysfunction; Progeria; Werner's syndrome.
4. **758.6:** Gondadal dysgenesis: Turner's Syndrome (female); XO syndrome
5. **759.81:** Prader-Willi Syndrome. **Genotropin**® is the only medication that has an indication for this diagnosis; requests for any other medication should contain information regarding why Genotropin cannot be used and forwarded to MDCH for review
6. **CRF & ESRD** (ICD-9 specific codes are not required). **CRF** is generally considered **Stage 4** and **ESRD Stage 5**. Chronic kidney disease may be referenced as **Stage 1-Stage 5**, with **Stage 1**/mildest and **Stage 5**/most severe. Additional info on Stage and GFR is on criteria page for **Epogen®.**

Diagnosis requiring MDCH physician review (icd-9 Code) forward to a clinical pharmacist:

1. **783.4**: Lack of expected normal physiological development Delayed milestone; failure to gain weight; failure to thrive; lack of growth; physical retardation; short stature
2. any other diagnosis code not listed above

Critical Information

- Growth hormone replacement medication included in **HIC3 P1A DO NOT** hit the **MAP: Injectables: non-Physician Service** edit.
- **Growth hormone stimulation testing:**
  1. *(7/2001 – clarification by CSHCS for CSHCS recipients) ~~ICD-9 **253.2** and~~ ICD-9 **253.3**: the child must have failed two kinds of growth hormone stimulation tests for the diagnosis; they cannot just be "low" in growth hormone.
  2. A normal peak value is at least 10 ng/mL; 5-10 ng/mL is indeterminate; 5ng.ML is subnormal. (A normal value

rules out human growth hormone deficiency; in some laboratories, the normal level is 7 ng/mL)

3. Requester should provide the reference range for the specific lab conducting the stimulation tests.

- **Bone age x-rays:**
  1. bone x-ray report for pediatric patients is required **UNLESS** the prescriber is a (pediatric) endocrinologist
  2. for teenage patients, have the requestor not whether or not the **ephysial growth plates** have closed
  3. bone x-ray report for adult patients is **NOT** required since it is usually not done.
- Requests that do not meet criteria and require MDCH review must include the patient's diagnosis including ICD_9, if available. Growth charts would also be helpful if available, at the time of review (ensure the correct chart is being submitted based on the patient's age – i.e., 0-3 vs 2-20) in addition to documentation of small gestational age at birth, if appropriate.

Michigan Department of Community Health (MDCH) PDL & MAP Criteria, Human Growth Hormone Replacement Therapy, November 15, 2010, page 111 (emphasis in original). (Exhibit 1, page 28)

The Appellant's [redacted], prior authorization request did not indicate a diagnosis in the above listing of "Diagnosis to approve." Accordingly, it should have been sent for a MDCH physician review. The Clinical Pharmacist explained that no further review of the [redacted], request occurred because the Appellant had a previous prior authorization request for Genotropin that was denied in [redacted] due to insufficient information and the physician reviewer had requested specific additional information that was not addressed in the [redacted], prior authorization request. (Clinical Pharmacist Testimony and Exhibit 1, page 1A) The physician reviewer's [redacted] denial note requested:

> Please clarify the diagnosis in light of lab results (is it short stature or fetal growth retardation?). Also, clarify the comment in note of [redacted] when the comment that wt and ht showed satisfactory interval gain. (Exhibit 1, page 19)

The physician reviewer's request was copied onto the [redacted], Notice of Prior Authorization Determination. (Exhibit 1, page 20)

The evidence indicates that [redacted] failed to process the Appellant's [redacted], prior authorization request in accordance with the Department of Community Health PDL & MAP criteria for Human Growth Hormone Replacement Therapy. [redacted] could not have approved this request because the diagnoses listed were not any of the listed "Diagnosis to approve." However, the policy then required that the request be sent for MDCH physician review.

Further, the [redacted], prior authorization did include additional information regarding the Appellant's diagnosis compared to the information submitted with the [redacted] prior authorization request. (Exhibit 1, pages 1-16 and 22) [redacted] erred in issuing the [redacted], Notice of Prior Authorization Determination indicating "N/A" as the prior authorization status and noting the denial information from the [redacted] denial. No notification of denial was sent to the Appellant or his doctor's office. In effect, the Department failed to make a determination on the [redacted], prior authorization request.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, must find that the Department did not process and make a determination on the Appellant's [redacted], prior authorization request.

IT IS THEREFORE ORDERED that:

The Department's decision is REVERSED. It is therefore ORDERED that the Department process the Appellant's [redacted], prior authorization request and consider the additional medical documentation that has been submitted.

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

cc: [redacted]

Date Mailed: 8/22/2011

***** 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.