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:

[redacted],

Appellant
_____/

Docket No. 2009-31302 QHP
Case No. [redacted]

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge 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], for the [redacted] and the Appellant's representative, appeared and testified on behalf of Appellant. [redacted], a Department contracted Medicaid Health Plan, represented the Department.

ISSUE

Did the Department properly deny Appellant's prior authorization request for Tev Tropin?

FINDINGS OF FACT

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

1. Appellant is a [redacted] female Medicaid beneficiary.

2. The Appellant is treating with a pediatric endocrinologist due to a diagnosis of Idiopathic Short Stature. She stands [redacted] inches tall [redacted] and weighs [redacted]. (uncontested)

3. The Appellant's laboratory tests do not reveal a deficiency of human growth hormone, however, her body does not respond adequately to its

own production of human growth hormone. (testimony of Appellant's representative)

4. In [redacted], the Appellant's physician requested prior authorization for the human growth hormone known as Tev-Tropin. (uncontested)

5. The Appellant's Medicaid Health Plan denied the request. It was appealed internally. (uncontested)

6. The Health Plan denied all internal appeals and requests for all human growth hormone drugs requested on behalf of the Appellant. (uncontested)

7. The Health Plan's most recent denial for the treatment sought occurred in [redacted]. (uncontested)

8. On [redacted], the State Office of Administrative Hearings and Rules received a hearing request, filed on Appellant's behalf, protesting the denial.

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 Department is authorized by federal law to develop a formulary of approved prescriptions and a prior authorization process. *MDCH Medicaid Provider Manual, Pharmacy Section.* The Department's contractor, [redacted], in this case, provided testimony that the treatment sought is not approved for the diagnosis of the Appellant. Michigan Medicaid, through the Department of Community Health prior authorization process authorizes coverage of this treatment for the following pathology diagnoses:

- Panhypopituitarism
- Pituitary dwarfism
- Endocrine disorders
- Gonadal dysgenesis: Turner's Syndromne (female)
- Prader-Willi Syndrome

Diagnoses that require MDCH physician review and fall under the ICD Code:

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…

The Department's Medicaid Provider Manual, Pharmacy Section states at 8.6 Prior Authorization:

A prior authorization will be denied if:

- The medical necessity is not established,
- If alternative medications are not ruled out,
- Evidence-based research and compendia does not support,
- It is contraindicated, inappropriate standard of care,
- Documentation required was not provided

Medicaid Provider Manual, Version Date 7/1/2007, p.16

The Appellant contests the denial of the treatment, asserting it is approved by the FDA for use in children with ISS diagnosis. Additionally, a claim of medical necessity is asserted citing future medical problems if the Appellant is unable to reach normal, adult height. It was indicated by the Appellant's nurse and hearing representative, that without reaching at least 5', the Appellant would be considered disabled. The witness continued, presenting uncontested testimony that the Appellant would be unable to operate a motor vehicle, nor would she would be unable to carry a pregnancy to full term. The Appellant did not assert she met any of the normally covered diagnoses.

The Department representative provided evidence to establish that Appellant does not have any of the above diagnoses, nor does she have a known pathology associated with her short stature. She stated the diagnosis suffered by the Appellant is not a covered diagnosis.

Consultation with the Michigan Department of Community Health Preferred Drug List confirms the drug requested requires clinical prior authorization. Unfortunately, this removes the determination of whether the treatment sought is a covered service from the Appellant's guardian and doctors and places it in the control of Department policies. The Department has established policy relative to the treatment sought for the Appellant's diagnosis and does not see fit to provide coverage. While this ALJ is not unsympathetic to the Appellant, this ALJ does not have the authority to determine the Department's policy is wrong. Department error can only be found if it is true the Department has applied it policy incorrectly. The uncontested material facts of this case determine its outcome. It is uncontested the Appellant suffers from Idiopathic Short Stature and is not reaching a normal adult height. The diagnosis she has is not a covered diagnosis for the treatment sought. No coverage for the treatment sought can be authorized by the Department.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, decides that the Department properly denied Appellant's request for human growth hormone.

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: _____11/17/2009_____

***** NOTICE *****

The State Office of Administrative Hearings and Rules 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 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.