

**STATE OF MICHIGAN
STATE OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
FOR THE DEPARTMENT OF COMMUNITY HEALTH**

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IN THE MATTER OF:

██████████,

Appellant

_____ /

Docket No. 2010-54283 QHP
Case No. ██████████

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

After due notice, a hearing was held on ██████████. ██████████, represented the Appellant. ██████████, represented ██████████, the Medicaid Health Plan (MHP). ██████████ appeared as a witness for the MHP.

ISSUE

Did the MHP properly deny the Appellant's request for the growth hormone therapy Saizen?

FINDINGS OF FACT

Based on the competent, material, and substantial evidence presented, the Administrative Law Judge finds, as material fact:

1. The Appellant is currently enrolled in the Respondent MHP, ██████████.
2. The Appellant is a ██████ year-old Medicaid beneficiary, who has been diagnosed with Idiopathic Short Stature (ISS). (Exhibit 1, pages 4-6)
3. On ██████████, the MHP received a request for Saizen from the Appellant's physician, ██████████. (Exhibit 1, pages 4-9)
4. On ██████████, the MHP sent the Appellant a denial notice, stating that the prior authorization request for Saizen was denied because the medication is not a covered benefit for the Appellant's diagnosis. (Exhibit 1, pages 2-3)

5. The Appellant requested a formal administrative hearing contesting the denial on ██████████.

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.

On May 30, 1997, the Department received approval from the Health Care Financing Administration, U.S. Department of Health and Human Services, allowing Michigan to restrict Medicaid beneficiaries' choice to obtain medical services only from specified MHPs.

The Respondent is one of those MHPs.

The covered services that the Contractor has available for enrollees must include, at a minimum, the covered services listed below (List omitted by Administrative Law Judge). The Contractor may limit services to those which are medically necessary and appropriate, and which conform to professionally accepted standards of care. The Contractor must operate consistent with all applicable Medicaid provider manuals and publications for coverages and limitations. If new services are added to the Michigan Medicaid Program, or if services are expanded, eliminated, or otherwise changed, the Contractor must implement the changes consistent with State direction in accordance with the provisions of Contract Section 2.024.

*Section 1.022(E)(1), Covered Services.
MDCH contract (Contract) with the Medicaid Health Plans,
October 1, 2009.*

- (1) The major components of the Contractor's utilization management (UM) program must encompass, at a minimum, the following:
 - (a) Written policies with review decision criteria and procedures that conform to managed health care industry standards and processes.

- (b) A formal utilization review committee directed by the Contractor's medical director to oversee the utilization review process.
- (c) Sufficient resources to regularly review the effectiveness of the utilization review process and to make changes to the process as needed.
- (d) An annual review and reporting of utilization review activities and outcomes/interventions from the review.
- (e) The UM activities of the Contractor must be integrated with the Contractor's QAPI program.

(2) Prior Approval Policy and Procedure

The Contractor must establish and use a written prior approval policy and procedure for UM purposes. The Contractor may not use such policies and procedures to avoid providing medically necessary services within the coverages established under the Contract. The policy must ensure that the review criteria for authorization decisions are applied consistently and require that the reviewer consult with the requesting provider when appropriate. The policy must also require that UM decisions be made by a health care professional who has appropriate clinical expertise regarding the service under review.

*Section 1.022(AA), Utilization Management, Contract,
October 1, 2009.*

The DCH-MHP contract provisions allow prior approval procedures for UM purposes. The MHP representative explained that for growth hormone therapy, the MHP requires prior approval. Under the [REDACTED], specific criteria must be met to achieve prior approval, and growth hormone therapy is not a covered benefit in certain situations, including for a diagnosis of Idiopathic Short Stature. (Exhibit 1, pages 11-22) The coverage guidelines require that the patient meet all of the following conditions before a growth hormone therapy is considered medically necessary and can be authorized:

1. GH is FDA-approved for member's medical condition/diagnosis.
2. Member is under 18 years of age. *if member is ≥18 years of age, reference "adult criteria"

3. Treating practitioner is a pediatric endocrinologist **OR** Member has been evaluated by a pediatric endocrinologist who recommends therapeutic intervention and will manage treatment.
4. Documentation of an abnormal growth velocity, in conjunction with a height and bone age that is less than chronological age for gender, as defined below:
 - a. Height: Baseline height must be < the third percentile or > 2 standard deviations [SD] below the mean for gender and age, a measure of the degree of short stature.
 - b. Growth velocity: Children aged ,3 years must have a pretreatment growth rate of < 7 cm per year, and children aged 3 years and older must have a growth rate < 4 cm per year.
5. Documentation of subnormal response to at least **TWO** standard GH stimulation tests (with insulin, levodopa, arginine, propanolol, clonidine, or glucagon) defined by a peak measure of GH level less than 10 mg/l after stimulation.

NOTE: For children with the following conditions, only **ONE** failed GH stimulation tests is required:

- Central nervous system tumors
 - Cranial irradiation
 - Panhypopituitarism
6. Documentation of open epiphyses as determined by X-ray
 7. Documentation of normal thyroid function (either endogenous or with thyroid hormone replacement therapy)
 8. Documentation/chart notes that intracranial malignancy or tumor, growth inhibiting medication, chronic disease, and endocrine disorders has been ruled out. *

*MRI documenting pituitary abnormality is recommended but not required for authorization. MRI without contrast is sufficient; MR contrast helpful if anatomy is not normal on regular MRI.

Note: if history of malignancy exists, member should be free of recurrence for at least that past six (6) months.

9. Member has no contraindications to GH therapy (e.g. Pregnancy, proliferative or preproliferative diabetic retinopathy, Pseudotumor cerebri or benign intracranial HTS) –Refer to ‘Exclusions’ section
10. Dosage prescribed is within the FDA-approved labeling based on member’s confirmed diagnosis.

(Exhibit 1, page 12)

The MHP witness explained that in this case, the growth hormone was denied because it is not a covered benefit for the Appellant’s diagnosis, Idiopathic Short Stature. (See Exhibit 1, pages 11 and 20) Further, the MHP’s Medical Director explained that the Appellant did not meet the coverage guidelines such as number 5 above. The Appellant has only had one test for growth hormone deficiency, which was normal. (Exhibit 1, page 6)

The Appellant’s mother disagrees with the denial. However, she acknowledged that the Appellant has been diagnosed with ISS, meaning the reason for his short stature is unknown. The Appellant’s mother explained that the normal treatment for this diagnosis would be “IGF-1” but due to the Appellant’s weight, treatment with “IGF-1” would likely cause him to develop diabetes. She stated that the Appellant’s doctors want to try treatment with growth hormone first to see if this will stimulate growth. The Appellant’s mother explained her understanding was that even though her son is producing growth hormone, his body it is not being converting it into “RF1” so he will grow. Therefore, the Appellant’s doctors want to try over stimulating the Appellant’s body with growth hormone as this may trick his body into producing “RF1.” (Mother’s Testimony)

While this ALJ sympathizes with the Appellant’s situation, the documentation provided does not support that he has met the criteria for prior approval of growth hormone therapy. It is uncontested that the Appellant has been diagnosed with Idiopathic Short Stature. The requested growth hormone therapy is specifically excluded from coverage for this diagnosis under the MHP coverage guidelines. Further, there is no documentation that the Appellant is deficient in growth hormone. Rather, the evidence indicates that despite a normal growth hormone test result, the Appellant’s doctors plan to treat him with growth hormone as an experiment to see if they can trick his body into growing. As described, this would not be the traditional, FDA approved usage of this medication.

Accordingly, the Appellant has not met his burden of proving that the MHP improperly denied his request for the growth hormone. This does not imply that he is not deserving of treatment, only that the coverage guidelines do not allow for coverage of this medication in his circumstances. The MHP’s denial is upheld.

[REDACTED]
Docket No. 2010-54283 QHP
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DECISION AND ORDER

The ALJ, based on the above findings of fact and conclusions of law, decides that the MHP properly denied the Appellant's request for the growth hormone Saizen.

IT IS THEREFORE ORDERED that:

The MHP's decision is AFFIRMED.

Colleen Lack
Administrative Law Judge
for Janet Olszewski, Director
Michigan Department of Community Health

cc:

[REDACTED]

Date Mailed: 11/29/2010

***** 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.

