

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████,
Petitioner,

v

File No. 149820-001

Blue Cross Blue Shield of Michigan,
Respondent.

Issued and entered
this 23rd day of October 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a prescription drug by his health plan. On September 14, 2015, ██████████ the Petitioner's authorized representative,¹ filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* After a preliminary review of the material submitted, the Director accepted the request on September 21, 2015.

The Petitioner receives prescription drug benefits through a plan that is underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM provided its response on September 24, 2015.

To address the medical issue in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on October 5, 2015.

II. FACTUAL BACKGROUND

The Petitioner's drug benefits are defined in BCBSM's *Preferred Rx Program Certificate*

¹ The Petitioner is a minor (██████████); his father authorized ██████████ to represent him.

*SG*² (the certificate).

When the Petitioner's doctor asked BCBSM to authorize the prescription drug Genotropin to treat his growth hormone deficiency, BCBSM denied the request, saying that the Petitioner does not meet its criteria for coverage.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its decision in a final adverse determination dated August 21, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for the prescription drug Genotropin?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM quoted a clinical pharmacist who reviewed the Petitioner's case and explained the reason for the denial:

The coverage guidelines for [the Petitioner's] Customer Select Drug List require criteria be met before coverage can be authorized. Our criteria for coverage of this medication require documentation of a diagnosis of growth hormone deficiency with hypopituitarism when one of the following criteria (a or b) are met:

- a) Two pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement such as TSH, ACTH, Gonadotropins, and ADH and both of the following i and ii:
 - i.) At least one known cause for pituitary disease or a condition affecting pituitary function, including pituitary tumor, surgical damage, hypothalamic disease, irradiation, trauma or infiltrative disease (histoplasmosis, Sheehan syndrome, autoimmune hypophysitis, or sarcoidosis) is documented, and
 - ii.) ONE provocative stimulation less than 5 ng/ml. The insulin tolerance test is the preferred testing method.

OR

² BCBSM form 910F, effective 2015.

- b) Three pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement AND an IGF-1 level below 80 ng/ml.

We have no record that this criterion has been met.

Petitioner's Argument

In a September 10, 2015, letter submitted with the external review request, the Petitioner's authorized representative wrote:

Please consider the following which compels [the] request for continued growth hormone therapy for [the Petitioner]. Medical history is significant for pediatric growth hormone therapy.

Clinical Findings:

- Diagnosis: Transition Adult Hormone Deficiency
- Height: 174 cm
- Weight: 63 kg
- October 3, 2014 IGF-1 136 ng/ml (rr: 180-501) and IGFBP-3 2.3 mg/L (rr: 2.5-4.8). Labs drawn 6 months after growth hormone therapy was discontinued
- June 30, 2015 provocative stimulation test, using Glucagon and Arginine, peaked at 1.4 ng/ml, respectively. This provides objective documentation of growth hormone deficiency.

The FDA approved the use of growth hormone replacement therapy for treatment of this diagnosis in August 1996. It is stated in the "Growth Hormone Guidelines." Endocrine Practice 2003; (No. 1) that "The only approved indication [for adults] was pituitary disease from known causes, including pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, trauma, and reconfirmed childhood GHD.

The Endocrine Society and American Association of Clinical Endocrinologist established guidelines for growth hormone therapy for adults and transition patients which states "We recommend that patients with childhood-onset GHD who are candidates for GH therapy after adult achievement be retested for GHD unless they have known mutations, embryopathic lesions causing multiple hormone deficits, or irreversible structural lesions/damage." The guidelines go on to further state that "the presence of a low IGF-1 also increases the likelihood that this diagnosis is correct" and "when glucagon is used as a stimulation test a cut-point between 2.5 and 3 ug/liter seems to have appropriate specificity and sensitivity for the diagnosis of GHD."

* * *

Based upon [the Petitioner's] clinical condition, scientific evidence, and present standards of care, GH Therapy is medically necessary. We request that the previous denial be overturned and this medication be approved in order for [the Petitioner] to avoid the negative physical consequences associated with growth hormone deficiency.

Director's Review

The question of whether BCBSM correctly denied coverage for Genotropin was presented to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is certified by the American Board of Pediatrics with a subspecialty in Pediatric Endocrinology; is a staff physician in endocrinology at a children's hospital; is published in the peer reviewed literature; and is in active practice. The IRO report made this recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for the prescription drug Genotropin be overturned.

After reviewing the record, including the criteria in BCBSM's Custom Select Drug List, the IRO reviewer explained why Genotropin was medically necessary in the Petitioner's case:

Clinical Rationale for the Decision:

In patients treated with GH for childhood GH deficiency, studies support the continuation of GH therapy through the transition period between childhood and adulthood until accrual of peak bone mass. The appropriate method and cutoff value for retesting of GH deficiency during the transition period is a subject of debate, but this enrollee had both a low IGF-1 level and an extremely low response on glucagon/arginine provocative testing. The enrollee thus meets standard criteria for GH deficiency during the transition period based on the American Association of Clinical Endocrinology guidelines. GH therapy is expected to maximize cardiovascular health, improve muscle stamina, and improve bone mineral density.

The enrollee has GH deficiency and should be treated during the transition period based on low IGF-1 level and poor results on provocative GH testing. Therefore, the prescription drug Genotropin is medically necessary for the enrollee's condition.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the IRO's recommendation is afforded

deference by the Director. In a decision to uphold or reverse an adverse determination the Director must cite “the principal reason or reasons why the [Director] did not follow the assigned independent review organization’s recommendation.” MCL 550.1911(16)(b). The IRO’s analysis is based on experience, expertise, and professional judgment and the Director can discern no reason why that analysis should be rejected in the present case.

Therefore, the Director adopts the IRO recommendation and finds that Genotropin is medically necessary to treat the Petitioner growth hormone deficiency.

V. ORDER

The Director reverses BCBSM’s August 21, 2015, final adverse determination. BCBSM shall immediately cover the prescription drug Genotropin and shall, within seven days of providing coverage, furnish the Director with proof it implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free telephone number (877) 999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than 60 days from the date of this order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin
Director

For the Director:



Randall S. Gregg
Special Deputy Director