

**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. 154015-001

Blue Cross Blue Shield of Michigan,  
Respondent.

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Issued and entered  
this 5<sup>th</sup> day of July 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

██████████ (Petitioner) was denied coverage for a prescription drug by his health insurer, Blue Cross Blue Shield of Michigan (BCBSM).

On June 6, 2016, ██████████, RN, the Petitioner's authorized representative, 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 June 13, 2016.

The Petitioner receives prescription drug benefits through a plan that is underwritten by 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 responded on June 16, 2016.

To address the medical issue in this case, the Director assigned it to an independent medical review organization, which provided its analysis and recommendation on June 28, 2016.

## II. FACTUAL BACKGROUND

The Petitioner's drug benefits are described in BCBSM's *Preferred Rx Program Certificate SG* (the certificate).

When the Petitioner's doctor asked BCBSM to cover 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's authorized representative 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 May 20, 2016. The Petitioner now seeks a review of that final adverse determination from the Director.

## III. ISSUE

Did BCBSM correctly deny coverage for Genotropin?

## IV. ANALYSIS

### BCBSM's Argument

In its final adverse determination, BCBSM quoted its 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, Genotropin, 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 thyroid stimulating hormone (TSH), adrenocorticotrophic hormone (ACTH), gonadotropins, and anti-diuretic hormone (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
- b. Three pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement and an insulin-like growth factor (IGF-1) level below 80 ng/ml. We have no record that this criterion has been met for this member.

### Petitioner's Argument

In a June 2, 2016, letter submitted with the external review request, the Petitioner's authorized representative wrote:

. . . [The Petitioner's] Medical history is significant for right bundle branch block, fatigue, memory impairment, visual hallucinations, and decrease muscle mass.

[The Petitioner's] clinical information can be summarized as follows:

- Growth hormone deficiency
- Hypogonadism
- Traumatic brain injury
- Multiple concussions
- December 10, 2015 IGF-1 163 ng/mL (rr.: 90-360)
- December 10 2015 provocative stimulation, using Insulin and Glucagon, peaked at 1.0
- MRI: Scattered foci of nonspecific, chronic white matter change

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; 9 (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 [*growth hormone deficiency*]."

\* \* \*

***Based upon [the Petitioner's] clinical condition, scientific evidence, and present standards of care, GH Therapy is medically necessary. It seems reasonable that he should be afforded the opportunity to receive the available known effective treatment for his condition. We respectfully request the current denial be overturned and the GH therapy be approved to treat the symptoms that are effecting [sic] [the Petitioner's] overall quality of life.***

### 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 Internal Medicine with a subspecialty in endocrinology, diabetes, and metabolism; a member of the American Diabetes Association and the American Academy of Clinical Endocrinologists; published in the peer reviewed literature; and in active clinical practice. The IRO reviewer presented the following analysis and recommendation:

#### **Reviewer's Decision and Principal Reasons for the Decision:**

##### **Is the prescription drug Genotropin medically necessary for treatment of the enrollee's condition?**

No. It is the determination of this reviewer that the prescription drug, Genotropin is not medically necessary for the treatment of the enrollee's condition.

##### **Are BCBSM's coverage guidelines and criteria consistent with the current generally accepted standard(s) of medical practice for treatment of the enrollee's condition?**

Yes. It is the determination of this reviewer that the BCBSM's coverage guidelines and criteria are consistent with the current generally accepted standard of medical practice for the treatment of the enrollee's condition. The BCBSM coverage guidelines and criteria require, essentially, incontrovertible evidence of hypopituitarism. However in this case, the IGF-1 is well within the normal range, so GHD is not present. There are not two (2) other pituitary hormone deficits.

#### **Clinical Rationale for the Decision:**

The Growth Hormone Guidelines indicate that patients should be evaluated for GHD if there is an obvious pituitary or hypothalamic injury or surgery and symptomatology consistent with GHD.

The enrollee does not have laboratory evidence of GHD as the IGF-1 is 163, which is within normal limits. The normal IGF-1 argues against GHD. In addition, the symptoms for which the enrollee is being evaluated for are unclear and nonspecific (fatigue, amnesia, low libido, difficulty focusing). Therefore, per the documentation submitted for review and national guidelines, the prescription drug Genotropin is not medically necessary for the treatment of this enrollee.

**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 upheld.

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 the IRO's recommendation should be rejected in this case. Therefore, the Director accepts the IRO recommendation and finds that Genotropin is not medically necessary to treat the Petitioner's growth hormone deficiency.

**V. ORDER**

The Director upholds BCBSM's final adverse determination of May 20, 2016.

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:



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Randall S. Gregg  
Special Deputy Director