

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

In the matter of:

██████████
██████████
Petitioner

v
Blue Cross Blue Shield of Michigan
Respondent

File No. 144714-001

Issued and entered
this 21st day of January 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On October 31, 2014, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review 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 November 10, 2014.

The Petitioner receives prescription drug benefits through a plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are defined in the *Blue Cross Premium Silver Benefits Certificate*. The Director 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 November 18, 2014.

To address the medical issue in the case, the Director assigned it to an independent medical review organization which provided its final analysis and recommendation on January 20, 2015.

II. FACTUAL BACKGROUND

The Petitioner is ██████ years old and has growth hormone deficiency. Her doctor requested coverage from BCBSM for the prescription drug Genotropin. BCBSM denied the request, ruling 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

October 3, 2014. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage of the prescription drug Genotropin to treat the Petitioner's condition?

IV. ANALYSIS

BCBSM's Argument

BCBSM wrote in its final adverse determination:

After review, the denial of prior authorization for Genotropin is maintained because you do not meet the clinical criteria for approval of Genotropin.

You are covered under the *Blue Cross Premier Silver Benefits Certificate*. In **Section 3: What BCBSM Pays For, under Prescription Drugs: Mandatory Prior Authorization** on pages 82 and 83 of the certificate, it states the following:

For some drugs certain clinical criteria must be met before coverage is provided. When prior authorization of a prescription drug is required, authorization must be obtained from [BCBSM] before we will consider payment of the drug.

If the required prior authorization is not requested or approval is not obtained, we will deny payment and you will be responsible for 100 percent of the pharmacy charge. The prescribing physician requesting prior authorization should demonstrate that the drug meets BCBSM's prior authorization criteria.

The coverage guidelines for your Customer Select Drug List require be met before coverage can be authorized.

Our criteria for coverage of this medication requires 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 a TSH, ACTH, Gonadotropins, and ADH and both of the following i and ii:
 - i: At least one known cause of pituitary disease or a condition affecting pituitary function, including pituitary tumor, surgical damage, hypothalamic disease, irradiation, trauma, or infiltrative disease

(histoplasmosis, Sheehan's syndrome, auto immune 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 IGF level below 80 ng/ml.

We have no record that this criteria has been met.

Petitioner's Argument

In a letter dated October 29, 2014, the Petitioner's authorized representative wrote:

Guidelines published by the American Association of Clinical Endocrinologists (ACCE) state: "All adults with substantiated growth hormone deficiency should be considered potential candidates for growth hormone replacement therapy. The goal is to correct the abnormalities associated with growth hormone deficiency and to prevent the development of abnormalities consequent to long-term deficiency in adults."

Please consider the following which compels the request for growth hormone treatment:

- Height: 63 inches
- Weight: 62 kg
- Hypothyroidism
- Adrenal insufficiency
- June 1, 2014 Insulin Tolerance Test/Glucagon peaked at 3.6 ng/mL
- IGF-1 117 ng/mL (rr: 94-252)
- July 21, 2014 MRI showed "no evidence of pituitary micro or macroadenoma"

* * *

[Petitioner's] abnormal stimulation test result confirms she is growth hormone deficient. While we may not know the exact cause of this deficiency, it is nonetheless there and denying growth hormone treatment will only place [Petitioner] at risk for multiple chronic complications and a lifelong change in her quality of living.

Director's Review

The necessity of Genotropin to treat the Petitioner's condition and the standards used by BCBSM to deny coverage were 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 board certified in clinical endocrinology and

metabolism and has been in practice for more than ten years. The IRO reviewer's report included the following analysis:

Growth hormone deficiency is a medical condition in which the body does not produce enough growth hormone. Recognized effects of growth hormone deficiency include reduced muscle mass and strength, reduced bone strength and osteoporosis, decreased energy levels, impaired concentration and loss of memory, increased body fat, lipid abnormalities and insulin resistance. (*J Clin Endocrinol Met.* 95(5):1621-34.) Growth hormone deficiency is also appreciated to be a factor in increased mortality from cardiovascular disease. (*Lancet.* 1990 Aug;8710(4):285-8....[G]rowth hormone replacement can provide a number of benefits to growth-hormone deficient adults including improved bone density, increased muscle mass, decrease of adipose tissue, faster hair and nail growth, a strengthened immune system, increased circulatory system and improved blood lipid levels. (*Hormone Research.* 53:37-41.) In patients with known hypothalamic or pituitary disease, doctors can establish the diagnosis of growth hormone deficiency with high sensitivity and specificity when there are 3 or 4 additional pituitary hormone deficiencies or a sub-normal IGF-1 level....[P]rovocative growth hormone stimulation is required to establish a diagnosis in patients without these conditions. (*Endocr Dev.* 2010;18:55-66.)...[A]ccording to general standards of care for diagnosis and treatment of growth hormone deficiency, the member meets the criteria for growth hormone deficiency because she has a history of hypopituitarism, resulting in adrenal insufficiency and growth hormone deficiency and exhibits a subnormal IGF-1 level of 117 ng/dl.

[T]he Health Plan's criteria for approving coverage of Genotropin are not the correct standards to be applied in this case...the American Association of Clinical Endocrinology (AACE) guidelines should be applied....[A]ccording to AACE guidelines, all adults with substantial growth hormone deficiency should be considered potential candidates for growth hormone therapy....[T]he member meets the AACE guidelines for growth hormone therapy because she demonstrated a sub-normal growth hormone response to dynamic testing with a glucagon peak response of 3.6 ng/ml.

...Genotropin is medically necessary for treatment of the member'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 extensive experience, expertise, and professional judgment.

The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that Genotropin is medically necessary to treat the Petitioner's condition.

V. ORDER

The Director reverses BCBSM's denial in its October 3, 2014, final adverse determination. BCBSM shall, within 60 days of the date of this order, provide coverage for the prescription drug Genotropin for the Petitioner, and shall, within seven days of providing coverage, furnish the Director with proof it has complied with 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, at the toll free 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.

Annette E. Flood
Director

For the Director:



Randall S. Gregg
Special Deputy Director