

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. 153890-001

Blue Cross Blue Shield of Michigan,

Respondent.

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Issued and entered  
this 24<sup>th</sup> day of June 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

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

On May 26, 2016, ██████████, 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 3, 2016.

The Petitioner receives prescription drug benefits through a plan 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 9, 2016.

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 June 17, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are described in BCBSM's *Preferred Rx Program Certificate LG* (the certificate) and *Rider PD-TTC \$10/\$40/\$80-RXCM LG Prescription Drug Triple-Tier Copayment with a Cost Management Program* (the rider).

The Petitioner's physician 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 and the drug is therefore not medically necessary.

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 April 19, 2016. 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 to treat the Petitioner?

### IV. ANALYSIS

#### BCBSM's Argument

In its final adverse determination to Petitioner's authorized representative, BCBSM's reviewer, a clinical pharmacist, wrote:

Genotropin is a medication that requires preauthorization to determine if criteria were met. For this reason, a Clinical Pharmacist, RPh reviewed the submitted documentation and determined the following:

. . . The coverage guidelines for your Custom Drug List benefit 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 and 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 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.
- 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 criteria has been met.

#### Petitioner's Argument

In a March 28, 2016, letter that was submitted with the request for external review, the Petitioner's authorized representative wrote:

Please consider the following which compels [the Petitioner's physician's] request for growth hormone therapy for [him].

- Growth Hormone Deficiency
- Traumatic Brain Injury 2013
- Hypothyroidism
- Hypogonadism
- July 30, 2015 IGF-1 level 102 ng/mL, IGFBP-3 3.58 ng/mL, Testosterone 210 (241-877)
- July 30, 2015 provocative stimulation test, using Insulin and Glucagon, peaked at <0.1 ng/ml and provides objective documentation of adult growth hormone deficiency. . .

Growth hormone replacement is consistent with the guidelines published by the American Association of Clinical Endocrinologist (ACCE). The guidelines 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."

Genotropin growth hormone therapy can improve and /or eliminate the negative consequences of growth hormone deficiency.

\* \* \*

Given the results of [the Petitioner's] medical evaluation and the potential benefits of GH replacement therapy, please reconsider [the] previous denial of coverage. This physician-recommended therapy is approved by the FDA and is consistent with the AACE and GRS guidelines for this condition.

### Director's Review

The question of whether Genotropin is medically necessary to treat the Petitioner 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 board certified in endocrinology, has been in active practice for more than 10 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

#### **Standard of Review:**

In rendering its decision, MAXIMUS has interpreted the rights and responsibilities of the parties in accordance with applicable Michigan Law, the Health Plan's contract and ap-

plicable coverage guidelines and generally accepted principles guiding the provision of health care.

**Recommended Decision:**

The MAXIMUS physician consultant determined that growth hormone therapy is medically necessary for treatment of the member's condition.

**Rationale:**

\* \* \*

The results of the consultant's review indicate that this case involves a 61 year-old male who has a history of growth hormone deficiency, which is complicated by hypogonadism and hypothyroidism, as a result of a brain injury. At issue in this appeal is whether growth hormone therapy is medically necessary for treatment of the member's condition.

Growth hormone deficiency is a medical condition in which the body does not produce enough growth hormone. Recognized effects of this condition 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. Growth hormone deficiency is also appreciated to be a factor in increased mortality from cardiovascular disease. Growth hormone replacement therapy can provide a number of measurable benefits to growth-hormone deficient adults, including improved bone density, increased muscle mass, decrease of adipose tissue, faster hair and nail growth, strengthened immune system, increased circulatory system and improved blood lipid levels. 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 deficiencies or a sub-normal IGF-1 level. To establish this diagnosis in patients without these criteria, provocative growth hormone stimulation is required.

The member exhibited a subnormal IGF-1 and failed to mount an appropriate response to a growth hormone stimulation test using insulin and glucagon. The MAXIMUS physician consultant explained that the member meets the criteria for growth hormone deficiency. The physician consultant indicated that the member has a history of hypopituitarism resulting in hypogonadism and growth hormone deficiency and exhibited a sub-normal IGF-1 level of 102 ng/ml. The consultant also indicated that the member failed dynamic testing for growth hormone deficiency with a peak response to insulin and glucagon of 0.1 ng/ml. The physician consultant noted that the member does meet the Health Plan's criteria for coverage of growth hormone.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that growth hormone therapy is medically necessary for treatment of the member's condition. [References omitted]

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. In addition, the IRO’s recommendation is not contrary to any provision of the Petitioner’s coverage. MCL 550.1911(15). The Director, discerning no reason why the IRO’s analysis should be rejected in this case, adopts the IRO recommendation and finds that Genotropin is medically necessary to treat the Petitioner, and is a covered benefit under the certificate.

### V. ORDER

The Director reverses BCBSM’s April 19, 2016 final adverse determination.

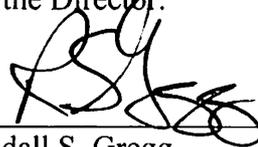
BCBSM shall immediately cover the prescription drug Genotropin for the Petitioner and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

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:



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Randall S. Gregg  
Special Deputy Director