

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. 151557-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this *2nd* day of February 2016
by **Randall S. Gregg**
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for human growth hormone therapy by his health insurance carrier, Blue Cross Blue Shield of Michigan (BCBSM).

On January 4, 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 information submitted, the Director accepted the request on January 11, 2016.

The Petitioner receives prescription drug benefits through an individual 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 provided its response on January 11, 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 January 25, 2016.

II. FACTUAL BACKGROUND

The benefits are defined in the *Blue Cross Premier Value Benefits Certificate*¹ (the certificate).

The Petitioner's physician asked BCBSM to authorize coverage for the prescription drug Genotropin for growth hormone therapy. BCBSM denied the request, saying that the Petitioner did not meet its criteria for coverage, i.e., it was 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 December 2, 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 to treat the Petitioner?

IV. ANALYSIS

Petitioner's Argument

In a December 30, 2015, letter submitted with the external review request, the Petitioner's authorized representative wrote:

This appeal . . . regarding the denial of coverage for Genotropin (somatropin [rDNA origin] for injection) recombinant growth hormone (GH), which has been approved by the Food and Drug Administration (FDA) for the treatment of adult growth hormone deficiency (GHD). . . .

Patient Condition

[The Petitioner] is a 27 year old patient under the care of [an] Endocrinologist, for adult onset growth hormone deficiency. Medical history is significant for Traumatic Brain Injury in 2008 that required plating to the forehead.

Symptoms:

- Fatigue
- Insomnia
- Cold Intolerance

¹ BCBSM form no. 601F.

- Hair Loss
- Dizziness
- Memory Impairment

[The Petitioner] underwent provocative stimulation testing on September 8, 2015, using Insulin and Glucagon, revealing a peak level of only 0.3 ng/ml with a Glucose of 64 mg/dL. The American Association of Clinical Endocrinologists recognizes response to provocative stimulation testing less than 5.0 ng/mL in adult patients, to be indicative of 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."

* * *

[The Petitioner's] documented traumatic brain injury and growth hormone stimulation testing provides objective documentation to support the diagnosis of growth hormone deficiency. This physician recommended therapy is consistent with the AACE and LWPES guidelines for this condition. We request that the previous denial be overturned and this medication be approved in order for [him] to avoid the negative physical consequences associated with growth hormone deficiency.

BCBSM's Argument

In its final adverse determination, BCBSM said:

... A Clinical Pharmacist RPh review[ed] the documentation provided and determined the following:

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 5ng/ml. The insulin tolerance test is the preferred method.

OR

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

We have no record that this criteria has been met for this member.

Director's Review

The question of whether Genotropin is medically necessary to treat the Petitioner's condition 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 12 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

The results of the consultant's review indicate that this case involves a ■ year-old male who has a history of a traumatic brain injury. At issue in this appeal is the request for authorization and coverage of Genotropin for treatment of the member's condition.

The MAXIMUS physician consultant indicated that the Health Plan's criteria for coverage of growth hormone therapy are consistent with current standards of medical care. The physician consultant also indicated that the member does not meet the Health Plan's criteria for coverage of growth hormone therapy at this time. The consultant explained that there was no other evidence in the records provided for review to indicate that the member has other pituitary hormone deficits. The physician consultant noted that the insulin intolerance test (ITT) requires true hypoglycemia, which is usually less than 35. In this case, the nadir glucose was 64. The consultant indicated that the glucose was not low enough to say that this was a true ITT. The consultant explained that therefore, the low growth hormone does not indicate growth hormone deficiency based on the records submitted in this case.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Genotropin is not medically necessary for treatment of the member's condition. [Citation 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 and the Director can discern no reason why that analysis should be rejected in the present case. Therefore, the Director accepts the IRO recommendation and finds that Genotropin is not medically necessary to treat the Petitioner.

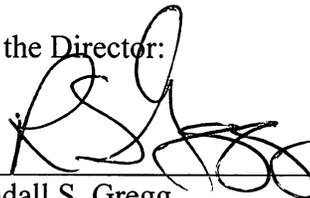
V. ORDER

The Director upholds BCBSM's December 2, 2015, final adverse determination.

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 Michigan 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