

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. 154269-001

Blue Care Network of Michigan
Respondent

Issued and entered
this 29th day of July 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 22, 2016, ██████████, mother of ██████████ (Petitioner), filed a request with the Department of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*¹

The Petitioner receives health care benefits through an individual plan underwritten by Blue Care Network of Michigan (BCN), a health maintenance organization. His prescription drug benefits are described in BCN's *Silver 70 Prescription Drug Rider*. The Petitioner's request for review challenges BCN's denial of coverage for Genotropin, a drug manufactured by Pfizer, Inc. that is used to treat growth failure in children.

The Director notified BCN of the external review request and asked for the information used to make its final adverse determination. BCN furnished information on June 27, 2016. On June 29, 2016, after a preliminary review of the information submitted, the Director determined the case was eligible for an external review.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on July 19, 2016.

II. FACTUAL BACKGROUND

The Petitioner, a 14-year-old male, has been prescribed Genotropin for growth failure

1. In this appeal, the Petitioner is represented by his mother and also by an authorized representative, ██████████, a registered nurse employed by Pfizer, Inc.

associated with idiopathic short stature. BCN was requested to provide coverage for the drug. BCN denied coverage indicating it does not cover Genotropin for a diagnosis of idiopathic short stature.

The Petitioner's physician appealed the denial through BCN's internal grievance process. BCN issued a final adverse determination on May 13, 2016, affirming the denial. The Petitioner, through his representatives, now seeks the Director's review of that determination.

III. ISSUE

Is BCN required to provide coverage for the prescription drug Genotropin to treat the Petitioner's condition?

IV. ANALYSIS

BCN's Argument

In its initial denial letter, BCN provided this justification for its coverage denial:

Blue Care Network cannot approve the request for [Genotropin] because certain conditions must be met before coverage is provided for this drug:

- Coverage is provided for pediatric growth hormone deficiency; growth failure or short stature in children small for gestational age or with intrauterine growth retardation; or associated with Turner's syndrome, chronic renal insufficiency (not post transplant), Noonan syndrome, SHOX deficiency, Prader-Willi syndrome; and treatment of severe burns.
- Coverage for growth hormone therapy for idiopathic short stature is not considered medically necessary, per plan medical policy. Based on the information submitted, the member does not have a required diagnosis, therefore coverage cannot be authorized at this time.

Later, final adverse determination BCN wrote:

We based our decision on the fact that the diagnosis of Idiopathic Short Stature is not covered for a growth hormone (GH) treatment such as Genotropin.

Petitioner's Argument

In the external review request the Petitioner's mother wrote:

I request an external review of Blue Care Network decision to deny the request for Genotropin growth hormone therapy. [The Petitioner] has an

FDA approved diagnosis for growth hormone therapy and [his doctor] deems treatment to be medically necessary in order for [the Petitioner] to achieve adequate growth to reach his final predicted adult height.

Jillian Knight, as an authorized representative of the Petitioner, submitted a letter and supporting documents describing idiopathic short stature and treatment with Genotropin, arguing that the drug should be a covered benefit.

Director's Review

BCN does provide coverage for drugs, including Genotropin, to treat growth deficiency in children. BCN's criteria for approval of coverage for Genotropin are found in its "Custom Select Drug List, Prior Approval and Step Therapy Guidelines" (page 10):

Children (<18 years of age): Coverage is provided for the treatment of growth hormone deficiency, growth failure secondary to chronic renal failure/ insufficiency who have not received a renal transplant, growth failure in children small for gestational age or with intrauterine growth retardation, Turner's Syndrome, Noonan's Syndrome, Prader-Willi Syndrome, SHOX deficiency, or for treatment of severe burns covering >40% of the total body surface area. The member's current height and weight must be provided. The member must also have open epiphyses.

- **Initial treatment:** For growth hormone deficiency, test results confirming diagnosis must be provided. The member's height must be below the 5th percentile, and confirmed open epiphyses.
- **To continue:** The member must achieve a growth velocity of > 4.5 cm/year while receiving therapy over the past year. Treatment may continue until final height or epiphyseal closure has been documented.

The Director requested that an independent review organization (IRO) review BCN's criteria for Genotropin and evaluate whether Genotropin is medically necessary for treatment of Petitioner's condition. This medical review is required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer in this case is a physician in active practice who is certified by the American Board of Pediatrics with a subspecialty in pediatric endocrinology and is published in peer reviewed medical literature. The reviewer's report included the following analysis and recommendation:

Is [BCN's] criteria the standard of care for this drug?

No. The BCN criteria is very narrow in scope and, while it does incorporate part of the current standard of care for this drug, it is not reflective of the current accepted standards in the pediatric endocrinology community. The Food and Drug Administration (FDA) criteria and criteria set by the Pediatric Endocrine Society for GH [growth hormone] treatment

are broader than the strict BCN criteria, which looks only at GH deficiency per se.

If not the standard of care, is this drug medically necessary for the treatment of the enrollee's condition?

Yes. See below.

Clinical Rationale for the Decision:

According to the Pediatric Endocrinology Society Guidelines a trial of GH therapy should be approved for children with otherwise unexplained short stature who pass GH stimulation tests but who meet most of the following criteria:

1. Height more than 2.25 standard deviations below the mean for age or more than 2 SD below the mid-parental height percentile;
2. Growth velocity < 25th percentile for bone age;
3. Bone age more than 2 SD below the mean for age;
4. Low serum IGF-1 and/or IGFBP-3; and/or
5. Other clinical features suggestive of GH deficiency.

This enrollee meets most of the above criteria. He has extreme short stature of unclear etiology with an adult predicted height of only 58 inches, based on the height measurement and bone age assessment in December 2015. The enrollee thus meets FDA indications for idiopathic short stature with very poor adult height prediction at less than 63 inches in a male.

The enrollee has poor growth velocity, a lower than expected IGF-1 level for bone age, and his epiphyses are still open. As such, continuation of GH therapy, which he has been receiving for the past three years, is appropriate. Withdrawing GH therapy in this enrollee with such extreme short stature at this point in time when there is limited window of opportunity to intervene, will not allow him to achieve a height that is at all close to his growth potential. Therefore, the drug Genotropin is medically necessary for the treatment of this enrollee.

It is the recommendation of this reviewer that the denial issued by Blue Care Network of Michigan for the drug Genotropin be overturned.

[References omitted.]

While the Director is not required in all instances to accept the IRO's recommendation, the recommendation is afforded deference by the Director. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). 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 certificate of coverage. See MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds the prescription drug Genotropin is medically necessary for treatment of the Petitioner's condition. Therefore, the drug is a covered benefit under the certificate.

V. ORDER

BCN's final adverse determination is reversed. BCN shall immediately provide prescription drug coverage for Genotropin for treatment of the Petitioner's condition. See MCL550.1911 (17). Further, BCN 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



Randall S. Gregg
Special Deputy Director