

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. 148244-001

Blue Cross Complete of Michigan,

Respondent.

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Issued and entered  
this 10<sup>th</sup> day of July 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On June 9, 2015, ████████████████████, authorized representative of ████████████████████ (Petitioner),<sup>1</sup> 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.*

The Petitioner receives health care benefits through Blue Cross Complete of Michigan (BCC), a health maintenance organization for Medicaid beneficiaries. The Director immediately notified BCC of the external review request and asked for the information it used to make its final adverse determination. The Director received BCC's response on June 15, 2015. After a preliminary review of the material submitted, the Director accepted the request on June 16, 2015. BCC submitted additional documentation on June 19, 2015.

This case involves a medical issue so the Director assigned it to an independent review organization which submitted its recommendation to the Director on June 30, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are defined in the BCC's *Member Handbook* (the handbook) which includes a certificate of coverage.

The Petitioner began using the drug Genotropin for growth hormone therapy in December 2013 when he was covered under another health plan. When his pediatric endocrinologist asked BCC to cover Genotropin, the request was denied on the basis that the Petitioner did not meet its criteria for the continued use of growth hormone therapy drugs.

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<sup>1</sup> The Petitioner is a minor ████████████████████ and his parents authorized ████████████████████ to represent him in this external review.

The Petitioner appealed the denial through BCC's internal appeal process. At the conclusion of that process, BCC upheld its initial denial and issued a final adverse determination dated April 15, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

### III. ISSUE

Did BCC correctly deny coverage for the continued use of Genotropin?

### IV. ANALYSIS

#### Petitioner's Argument

In a June 5, 2015, letter accompanying his request for an external review, the Petitioner's authorized representative explained:

[The Petitioner] has grown beautifully since starting growth hormone therapy. Most recent visit, April 7, 2015 he measured 162.6 cm and 31<sup>st</sup> percentile. Growth velocity, calculated March 22, 2014 through April 7, 2015, was 7.5 cm/year. June 25, 2014 bone age was read as [REDACTED] at chronological age of [REDACTED] and indicates growth plates are Open and [he] still has time to grow. [He] has responded to growth hormone therapy as a patient with growth hormone deficiency would be expected to.

The standard of care as set out by the Pediatric Endocrine Society regarding the use of growth hormone is: Growth Hormone Deficiency is a diagnosis about growth not about height. It was evident by [the Petitioner's] change in his growth pattern, a sub-optimal growth velocity, and delayed bone age that he was experiencing growth failure. [His] growth hormone deficiency is documented by laboratory evaluation and he had a clinical presentation that warranted the medical necessity for growth hormone therapy. The GH Research Society recommends "Patients with proven GHD should be treated with recombinant hGH as soon as possible after the diagnosis is made. The primary objectives of the therapy of GHD are normalization of height during childhood and attainment of normal adult height.

[The Petitioner's] medical records clearly show that continuation of growth hormone therapy is medical[ly] necessary. The FDA guidelines indicate that treatment with GH should continue until the child has reached final height, the epiphyses have closed, or the child no longer responds to treatment.

#### Respondent's Argument

In its final adverse determination, BCC explained its denial for the continued use of Genotropin to the Petitioner's authorized representative:

**Your appeal is denied.** Your appeal is denied because: criteria has not been met. After review of the documentation submitted, the pretreatment evaluation shows a height of 1.5 SD below the mean. The statewide adopted Michigan Association of Health Plans

(MAHP) clinical criteria require >2 SD below the mean. Criteria [have] not been met based on MAHP clinical criteria.

Director's Review

BCC will cover Genotropin if its prior authorization criteria are met:

- The physician has written for a FDA approved indication or other medically accepted use as per compendia . . . excluding the use for cosmetic purposes

\* \* \*

AND

- For patients with growth hormone deficiency states (adult and pediatric) either the appropriate information, diagnosis &/or laboratory information has been provided with the request. This includes Growth Hormone (GH) level in response to the preferred stimulatory test (i.e. Insulin Tolerance Test or Glucagon or Arginine) &/or Insulin Growth Factor 1 level indicative of GH deficiency. In addition, for pediatric patients, documentation of his or her growth velocity (below 4.5 cm/year), their height percentile for age and gender, how far below the standard deviation (SD) their height is for their age (at least 2 SD below normal), or how far below the SD their height is from their mid-parent height percentile (at least 2 SD below)

\* \* \*

AND

- The medication is recommended and prescribed by an endocrinologist

AND

- The medication is being prescribed at an appropriate dose

\* \* \*

If all of the above conditions are met, the initial request will be approved with a 6-month duration and requests for reauthorization will be approved for a 12 month duration. If all of the above criteria are not met, the request is referred to a Medical Director for medical necessity review.

The question of whether the Petitioner met BCC's criteria for continued use of Genotropin or whether it is otherwise medically necessary for the Petitioner to use Genotropin was presented to an IRO for analysis as required by MCL 550.1911(6).

The IRO physician reviewer is board certified in pediatric endocrinology and has been in active practice for more than eight years. The IRO report included the following analysis and recommendation:

**Recommended Decision:**

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

**Rationale:**

\* \* \*

. . . At issue in this appeal is the request for authorization and coverage for Genotropin for treatment of the member's condition.

The MAXIMUS physician consultant indicated that although the member does not meet the Health Plan's criteria for coverage of Genotropin, he meets the criteria for classic growth hormone deficiency. Growth hormone deficiency should be suspected in a child with a persistently subnormal growth rate with no other identifiable cause and in whom hypothyroidism, chronic illness, undernutrition and genetic syndromes have been excluded. The physician consultant noted that although children severely affected by growth hormone deficiency fail growth hormone stimulation tests, some children with growth hormone deficiency achieve stimulated growth hormone concentrations above the cutoffs that have been applied. The consultant indicated that a trial of growth hormone is appropriate for children with otherwise unexplained short stature who pass growth hormone stimulation tests, but meet most of the following criteria: (1) a height that is more than 2.25 standard deviations below the mean for age or more than 2 standard deviations below the midparental height percentile; (2) growth velocity that is below the 25<sup>th</sup> percentile for bone age; (3) bone age that is more than 2 standard deviations below the mean for age; (4) low serum insulin-like growth factor 1 (IGF-1) and/or insulin-like growth factor binding protein 3 (IGFBP3); and/or (5) other clinical features suggestive of growth hormone deficiency.

The diagnosis of growth hormone deficiency in childhood is a multifaceted process that requires a comprehensive clinical and auxological assessment, combined with biochemical tests of the growth hormone insulin-like growth factor axis and radiological evaluation. The evaluation of growth hormone deficiency in a short child, where short stature is defined as a height that is more than 2 standard deviations below the population mean, should not be initiated until other causes of growth failure, such as hypothyroidism, chronic systemic disease, Turner syndrome or skeletal disorder have been considered and appropriately excluded. The physician consultant noted that it is recognized that short stature is often the only feature present. Criteria for initiation of immediate investigation include severe short stature that is more than 3 standard deviations below the mean, a height that is more than 1.5 standard deviations below the mid-parental height, a height that is more than 2 standard deviations below the mean and a height velocity over 1 year that is more than 1 standard deviation below the mean for chronological age or a decrease in height standard deviation of more than 0.5 over 1 year in children over 2 years of age, a height velocity of more than 2 standard deviations below the mean over 1 year or more than 1.5 standard deviations below the mean sustained over 2 years in the absence of short stature, signs indicative of an intracranial lesions, signs of multiple pituitary hormone deficiency and neonatal symptoms and signs of growth hormone deficiency.

The MAXIMUS physician consultant indicated that the member meets the auxologic and biochemical criteria for growth hormone deficiency. The physician consultant explained that the member has failed a growth stimulation test with 2 separate agents, specifically

glucagon and insulin, his bone age is delayed and he has shown poor growth. The consultant noted that all other etiologies of short stature have been ruled out. The physician consultant explained that growth hormone therapy with Genotropin is appropriate for treatment of growth hormone deficiency.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Genotropin 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 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 certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that continued use of the growth hormone drug Genotropin is medically necessary for the Petitioner's condition and therefore a covered benefit.

#### V. ORDER

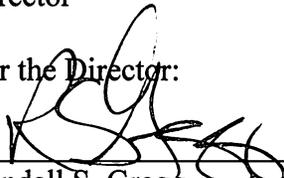
The Director reverses BCC's April 15, 2015, final adverse determination. BCC shall immediately cover the requested Genotropin growth hormone therapy and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Sections, 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 sixty 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 Director 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