oscar

Clinical Guideline

Guideline Number: PG049, Ver. 1

Growth Hormone

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member's plan contracts, state laws, and federal laws. Please reference the member's plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Growth hormone (GH) is produced by the pituitary somatotroph cells. GH production begins early in fetal life and continues throughout life, although at a progressively lower rate. The preferred growth hormone product is Humatrope (somatropin).

The plan covers the following FDA-approved indications: pediatric patients with growth failure due to any of the following - growth hormone (GH) deficiency, Turner syndrome, Noonan syndrome, small for gestational age (SGA), Prader-Willi syndrome, chronic kidney disease (CKD), short stature homeobox-containing gene (SHOX) deficiency and adults with childhood-onset or adult-onset GH deficiency. The plan also covers certain compendial uses for GH including human immunodeficiency, growth failure associated with any of the following - cerebral palsy, congenital adrenal hyperplasia, cystic fibrosis, and Russell-Silver syndrome. All other indications are considered experimental / investigational and are not a covered benefit (including idiopathic short stature).

All requests should be prescribed by or in consultation with one of the following specialties: endocrinologist, pediatric endocrinologist, geneticist, or pediatric nephrologist (for CKD only). Other growth hormone formulations are preferred for certain conditions. Coverage for Nutropin AQ (somatropin) is only provided when being prescribed for patients with CKD. Coverage for nutropin (somatropin) is only provided when being prescribed for a patient with Noonan syndrome. Coverage for Genotropin (somatropin), Norditropin (somatropin), or Omnitrope (somatropin) is only provided when being prescribed for a patient with Prader-Willi syndrome.

Definitions

"Growth hormone deficiency" is a condition characterized by growth failure and can be divided into congenital and acquired forms.

"Noonan syndrome" is an autosomal dominant condition that is associated with short stature and congenital heart disease (CHD).

"Prader-Willi syndrome" is a syndrome caused by the absence of expression of the paternally active genes on the long arm of chromosome 15.

"Russell-Silver syndrome" is a syndrome characterized by severe intrauterine growth restriction and postnatal growth retardation with a prominent forehead, triangular face, downturned corners of the mouth, and boxy asymmetry (hemihypertropy).

"Short Stature homeobox-containing (SHOX) deficiency" is a syndrome in which there are variants in the SHOX-containing gene on the X chromosome.

"Small for Gestational Age" is defined as a weight and/or length at birth that is at least -2 standard deviations (SD) below the mean for gestational age.

"Turner Syndrome" is a sex chromosome disorder caused by loss of part or all of an X chromosome.

Pediatric Growth Hormone Deficiency:

Medical Necessity Criteria for Initial Authorization

Oscar covers Humatrope (somatropin) when ONE of the following criteria are met:

1. Member is a neonate or was diagnosed with GH deficiency as a neonate; *or*
2. Member meets ALL of the following:
    a. Member has ONE of the following:
        i. Two pretreatment pharmacologic provocative GH tests with both results demonstrating a peak GH level <10 ng/mL; *or*
        ii. A documented pituitary or CNS disorder and a pre-treatment Insulin-like growth factor 1 (IGF-1) level > 2 standard deviations (SD) below the mean
    b. For members < 2.5 years of age at initiation of treatment, a pretreatment height > 2 standard deviations (SD) below the mean
    c. For members ≥ 2.5 years of age at initiation of treatment, a pretreatment height > 2 SD below the mean and 1 year height velocity is > 1 SD below the mean OR a pretreatment 1-year height velocity > 2 SD below the mean

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. Documentation that the member epiphyses are open; *and*
2. Member's growth rate is > 2 cm / year unless there is a documented clinical reason for lack of efficacy (i.e. on treatment less than a year, nearining final adult height)

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Small for Gestational Age:

Medical Necessity Criteria for Initial Authorization

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. Member meets ONE of the following:
    a. Member birth wate < 2500 g at gestational age >37 weeks
    b. Birth weight or length less than 3rd percentile for gestational age
    c. Birth weight or length ≥ 2 SD below the mean for gestational age
2. Pretreatment age is ≥ 2 years; *and*
3. Member failed to manifest catch up growth by age 2 (i.e. pretreatment height ≥ 2 SD below the mean); *and*
4. Epiphyses are open

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. Documentation that the member epiphyses are open; *and*
2. Member's growth rate is > 2 cm / year unless there is a documented clinical reason for lack of efficacy (i.e. on treatment less than a year, nearining final adult height).

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Turner Syndrome:

Medical Necessity Criteria for Initial Authorization

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. Diagnosis confirmed by karyotyping; *and*
2. Member's pretreatment height is less than 5th percentile for age; *and*
3. Epiphyses are open

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. Documentation that the member epiphyses are open; *and*
2. Member's growth rate is > 2 cm / year unless there is a documented clinical reason for lack of efficacy (i.e. on treatment less than a year, nearining final adult height).

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Growth Failure Associated with CKD, Cerebral Palsy, Congenital Adrenal Hyperplasia, Cystic Fibrosis, and Russell-Silver Syndrome:

Medical Necessity Criteria for Initial Authorization

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. For members < 2.5 years of age at initiation of treatment, a pretreatment height > 2 SD below the mean; *and*
2. For members ≥ 2.5 years of age at initiation of treatment, a pretreatment height > 2 SD below the mean and 1 year height velocity is > 1 SD below the mean OR a pretreatment 1-year height velocity > 2 SD below the mean; *and*
3. Epiphyses are open

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. Documentation that the member epiphyses are open; *and*
2. Member's growth rate is > 2 cm / year unless there is a documented clinical reason for lack of efficacy (i.e. on treatment less than a year, nearining final adult height).

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Prader-Willi Syndrome:

Medical Necessity Criteria for Initial Authorization

Oscar covers Humatrope (somatropin) when ONE of the following criteria are met:

1. Diagnosis confirmed by genetic testing demonstrating deletion in the chromosomal 15q11.2-q13 region; *or*
2. Diagnosis confirmed by genetic testing demonstrating maternal uniparental disomy in chromosome 15; *or*
3. Diagnosis confirmed by genetic testing demonstrating imprinting defects or translocations involving chromosome 15

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. Documentation of clinical benefit as defined by improvement or stabilization in the member's body composition and psychomotor function

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Noonan Syndrome:

Medical Necessity Criteria for Initial Authorization

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. Pretreatment height > 2 SD below the mean and 1 year height velocity is > 1 SD below the mean OR a pretreatment 1-year height velocity > 2 SD below the mean; *and*
2. Epiphyses are open

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. Documentation that the member epiphyses are open; *and*
2. Member's growth rate is > 2 cm / year unless there is a documented clinical reason for lack of efficacy (i.e. on treatment less than a year, nearining final adult height).

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

SHOX Deficiency:

Medical Necessity Criteria for Initial Authorization

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. Diagnosis is confirmed by molecular or genetic analyses; *and*
2. Pretreatment height > 2 SD below the mean and 1 year height velocity is > 1 SD below the mean OR a pretreatment 1-year height velocity > 2 SD below the mean; *and*
3. Epiphyses are open

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Oscar covers Humatrope (somatropin) when ALL of the following criteria are met:

1. Documentation that the member epiphyses are open; *and*
2. Member's growth rate is > 2 cm / year unless there is a documented clinical reason for lack of efficacy (i.e. on treatment less than a year, nearining final adult height).

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Adult GH Deficiency:

Medical Necessity Criteria for Initial Authorization

Oscar covers Humatrope (somatropin) when ONE of the following criteria are met:

1. Member has 2 pretreatment pharmacologic provocative GH tests and both results demonstrated GH levels < 5 ng/mL, unless the agent is Macrilen in which case a GH level of less than 2.8 ng/mL confirms the presence of adult GHD; *or*
2. Member has 1 pretreatment pharmacologic provocative GH test that demonstrated a GH level < 5 ng/mL AND a pr-treatment IGF-1 level that is low for age and gender, unless the agent is Macrilen in which case a GH level of less than 2.8 ng/mL confirms the presence of adult GHD; *or*
3. Member has a structural abnormality of the hypothalamus or pituitary and >3 documented pituitary hormone deficiencies; *or*
4. Member has childhood-onset GH deficiency and a congenital abnormality of the hypothalamus or pituitary

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Oscar covers Humatrope (somatropin) when ONE of the following criteria are met:

1. Documentation of clinical benefit defined by improvement in the member's serum IGF-1; *or*
2. Documentation that the GH dose will be increased in response to a low IGF-1 serum concentration

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Experimental or Investigational / Not Medically Necessary

Humatrope for any other indication is *not covered* by Oscar as it is considered experimental, investigational, or unproven (including idiopathic short stature).

References

1. Clayton PE, Cianfarani S, Czernichow P, et al. Management of the child born small for gestational age through to adulthood: a consensus statement of the International Societies of Pediatric Endocrinology and the Growth Hormone Research Society. J Clin Endocrinol Metab 2007; 92:804.
2. de Boer H, Blok GJ, Popp-Snijders C, et al. Monitoring of growth hormone replacement therapy in adults, based on measurement of serum markers. J Clin Endocrinol Metab 1996; 81:1371.
3. Genotropin [package insert]. New York, NY: Pfizer Inc.; April 2019.
4. Humatrope [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2016.
5. Norditropin [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; February 2018.
6. Nutropin AQ [package insert]. South San Francisco, CA: Genentech, Inc.; December 2016.
7. Omnitrope [package insert]. Princeton, NJ: Sandoz Inc.; June 2019.
8. Saizen [package insert]. Rockland, MA: EMD Serono Inc.; May 2018.
9. Zomacton [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; July 2018.

Clinical Guideline Revision / History Information

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