Humana.

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PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Humatrope (somatropin)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Omnitrope (somatropin) vials 5.8 mg QUANTITY LIMIT— per diagnosis, see **Dosage allowed**
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Humatrope (somatropin) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

Adult GROWTH HORMONE DEFICIENCY (GHD) - Adult or Childhood Onset

For **initial** authorization:

1. Member must have a documented 30-day trial and failure of Omnitrope 5.8 mg vial; AND
2. Member is 18 years of age or older; AND
3. Medication must be prescribed by an endocrinologist; AND
4. Member must have a diagnosis of GHD confirmed by **one** of the following:
   a) Chart notes documentation of acquired structural abnormality (*see Appendix*) of the hypothalamus or pituitary and ≥ 3 documented pituitary hormone deficiencies (*see Appendix*) with included lab results and reference ranges;
   b) Documented childhood-onset of GHD with a documented congenital abnormality (*see Appendix*) of the hypothalamus or pituitary;
   c) Two pre-treatment peak serum growth hormone (GH) concentration < 5 ng/mL by stimulation testing with included lab results and reference ranges, unless Macrilen (prior authorization required) was used, in which case a GH level must be < 2.8 ng/ml.
5. **Dosage allowed:** Weight based dosing: 0.006 mg/kg/day - 0.0125 mg/kg/day. Non-weight based dosing: starting dose 0.2 mg/day (0.15-0.30 mg/day) and increased every 1-2 months in increments of 0.1-0.2 mg/day, doses vary considerably.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all of the initial criteria; AND
2. Member's current IGF-1 level not elevated for age/gender (does not apply to members w/ structural abnormality of hypothalamus/pituitary and at least pituitary hormone deficiencies or childhood onset GHD and congenital abnormality of hypothalamus/pituitary).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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Pediatric GROWTH HORMONE DEFICIENCY (GHD)

For **initial** authorization:

1. Member must have a documented 30-day trial and failure of Omnitrope 5.8 mg vial; AND
2. Member is age 17 years of age or younger; AND
3. Medication must be prescribed by an endocrinologist; AND
4. Member must have a diagnosis of GHD confirmed by **one** of the following:
   a) Neonate or diagnosed with GHD as neonate indicated by ALL of the following:
      i) Chart notes, labs, and documentation must be included to support the diagnosis (e.g, hypoglycemia with random GH level ≤ 5 ng/mL, evidence of multiple pituitary hormone deficiency (*see Appendix*), MRI results);
      ii) Pituitary abnormality (secondary to congenital anomaly (*see Appendix*), pituitary tumor, or irradiation);
      iii) A known deficiency of at least one other pituitary hormone (*see Appendix*);
   b) Two pre-treatment peak serum growth hormone concentration < 10 ng/mL by stimulation testing (*must include lab results with reference ranges*);
   c) A documented pituitary or CNS disorder and a pre-treatment IGF-1 level > 2 Standard Deviations (SD) below the mean (*must include chart notes and documentation to confirm diagnosis and lab results with reference ranges*); AND
5. Member must have a pretreatment height (*must include growth charts*) of > 2 SD below the mean for age and gender; AND
6. If member is age 12 or older, radiographic evidence the member's epiphyses are open (*x-ray results must be included*). Comparison of bone age to chronological age should be documented as abnormal by > 2 SD below the mean for chronological age.
7. **Dosage allowed:** 0.18-0.30 mg/kg/week.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all of the initial criteria; AND
2. If member is age 12 or older, radiographic evidence the member's epiphyses are open (*x-ray results must be included*). Comparison of bone age to chronological age should be documented as abnormal by > 2 SD below the mean for chronological age; AND
3. Member has a growth rate > 2.5 cm/year unless there is a documented reason for lack of efficacy (on treatment < 1 year, off treatment for a reason for a period of time, nearing final adult height, late stages of puberty).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

SHOX DEFICIENCY

For **initial** authorization:

1. Member must have a diagnosis of SHOX gene deficiency confirmed by genetic analyses (*must include documentation*); AND
2. Medication must be prescribed by an endocrinologist; AND
3. Member's pre-treatment height is > 2 SD below the mean and 1 year height velocity is > 1 SD below the mean for age (*must include growth charts and documentation*); AND
4. If member is age 12 or older, the member's epiphyses are open, confirmed by radiograph of the wrist and hand (*x-ray results must be included*). Comparison of bone age to chronological age should be documented as abnormal by > 2 SD below the mean for chronological age.

5. **Dosage allowed:** 0.35 mg/kg/week.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all of the initial criteria; AND
2. If member is age 12 or older, the member's epiphyses are open, confirmed by radiograph of the wrist and hand (*x-ray results must be included*). Comparison of bone age to chronological age should be documented as abnormal by > 2 SD below the mean for chronological age; AND
3. Member has a growth rate > 2.5 cm/year unless there is a documented reason for lack of efficacy (on treatment < 1 year, off treatment for a reason for a period of time, nearing final adult height, late stages of puberty).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

SMALL for GESTATIONAL AGE (SGA)

For **initial** authorization:
1. Member must have a documented 30-day trial and failure of Omnitrope 5.8 mg vial; AND
2. Member is 2 years of age or older prior to initiating treatment; AND
3. Medication must be prescribed by an endocrinologist; AND
4. Member must have a diagnosis of small for gestational age (SGA) and failed to catch up growth by 2 years of age; AND
5. Member's birth weight and/or length are > 2 SD below the mean for gestational age (*must include growth charts and documentation*); AND
6. Member's height remains > 2 SD below population for age and gender (*must include growth charts and documentation*); AND
7. If member is age 12 or older, radiographic evidence the member's epiphyses are open (*x-ray results must be included*). Comparison of bone age to chronological age should be documented as abnormal by > 2 SD below the mean for chronological age.
8. **Dosage allowed:** Up to 0.47 mg/kg/week.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all of the initial criteria; AND
2. If member is age 12 or older, radiographic evidence the member's epiphyses are open (*x-ray results must be included*). Comparison of bone age to chronological age should be documented as abnormal by > 2 SD below the mean for chronological age; AND
3. Member has a growth rate > 2.5 cm/year unless there is a documented reason for lack of efficacy (on treatment < 1 year, off treatment for a reason for a period of time, nearing final adult height, late stages of puberty).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

TURNER SYNDROME

For **initial** authorization:
1. Member must have a documented 30-day trial and failure of Omnitrope 5.8 mg vial; AND
2. Member is female age 2 to 17 years; AND

3. Medication must be prescribed by an endocrinologist; AND
4. Member must have a diagnosis of Turner Syndrome confirmed by genetic analyses (*must include documentation*); AND
5. Member's pre-treatment height is > 2 SD below the mean and 1 year height velocity is > 1 SD below the mean for age (*must include growth charts and documentation*); AND
6. If member is age 12 or older, radiographic evidence the member's epiphyses are open (*x-ray results must be included*). Comparison of bone age to chronological age should be documented as abnormal by > 2 SD below the mean for chronological age.
7. **Dosage allowed:** Up to 0.375 mg/kg/week.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all of the initial criteria; AND
2. If member is age 12 or older, radiographic evidence the member's epiphyses are open (*x-ray results must be included*). Comparison of bone age to chronological age should be documented as abnormal by > 2 SD below the mean for chronological age; AND
3. Member has a growth rate > 2.5 cm/year unless there is a documented reason for lack of efficacy (on treatment < 1 year, off treatment for a reason for a period of time, nearing final adult height, late stages of puberty).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Humatrope (somatropin) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Constitutional growth delay
- Corticosteroid-induced growth failure
- Cystic fibrosis
- Idiopathic, or non-growth hormone dependent, short stature
- Juvenile idiopathic, or chronic, arthritis
- Noonan Syndrome
- Obesity
- Partial growth hormone deficiency
- Pediatric growth failure due to chronic kidney disease
- Prader-Willi Syndrome
- Wound healing in burns patients

DATE	ACTION/DESCRIPTION
10/25/2018	New policy for Humatrope created.

References:

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2. Cook DM, Yuen KCJ, Biller BMK, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Growth Hormone-Deficient Adults and Transition Patients – 2009 update. Endocr Pract. 2009; 15(2): 1-29.

3. Gharib H, Cook DM, Saenger PH, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use Adults and Children – 2003 update. Endocr Pract. 2003; 9(1): 64-76.
4. American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists Position Statement Growth Hormone Usage in Short Children. December 2003. https://www.aace.com/files/position-statements/shortchildren.pdf
5. Molitch ME, Clemmons Dr, Malozowski S, et al. Evaluation and treatment of adult growth hormone deficiency: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2011; 96: 1587-1609.
6. National Institute for Clinical Excellence: Guidance on the use of human growth hormone (somatropin) for the treatment of growth failure in children. May 2010.
7. National Institute for Clinical Excellence: Human growth hormone (somatropin) in adults with growth hormone deficiency. August 2003.
8. Wilson TA, Rose SR, Cohen P, et al. Update of guidelines for the use of growth hormone in children: The Lawson Wilkins Endocrinology Society Drug and Therapeutics Committee. J Pediatr. 2003; 143: 415-421.
9. Deal CL, Tony M, Hoybye C, et al. Growth Hormone Research Society workshop summary: consensus guidelines for recombinant human growth hormone therapy in Prader-Willi syndrome. J Clin Endocrinol Metab. 2013; 98: 1072-1087.
10. Blum WF, Crowe BJ, Quigley CA, et al. Growth hormone in effective in treatment of short stature associated with short stature homeobox-containing gene deficiency: two-year results of a randomized, controlled, multicenter trial. J Clin Endocinol Metab. 2007; 92: 219-228.
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15. Romano AA, Allanson JE, Dahlgren J, et al. Noonan syndrome: clinical features, diagnosis, and management guidelines. Pediatrics 2010;126(4): 746-759
16. 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 Endrocrinol Metab. 2007; 92(3): 804-810.
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18. Nemecheck PM, Polsky B, Gottlieb MS. Treatment Guidelines for HIV-associated wasting. May Clinc Proc. 2000; 27: 386-394.
19. Goldstone AP, Holland AJ, Hauffa BP, et al. Recommendations for the diagnosis and management of Prader-Willi Syndrome. J Clin Endocrinol Metab. 2008; 93: 4183-4197.
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21. Blum WF, Ross JL, Zimmermann Ag, et al. Growth hormone treatment to final height produces similar height gains in patients with SHOX deficiency and Tuner syndrome: results of a multicenter trial. J Clin Endocrinol Metab. 2013; 98 (8): 1383-1392.
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Effective date: 02/01/2019
Revised date: 10/25/2018

Appendix:

1) Acquired structural abnormalities:
   - CNS tumor or neoplasm (craniopharyngioma, glioma, pituitary adenoma, etc.)
   - Cysts (Rathke cleft cyst or arachnoid cleft cyst)
   - Surgery
   - Radiation
   - Chemotherapy
   - CNS infection
   - CNS infarction (e.g., Sheehan's syndrome)
   - Inflammatory lesions (e.g., autoimmune hypohysitis)
   - Infiltrative lesions (e.g., sarcoidosis, histiocytosis)
   - Head trauma or traumatic brain injury
   - Aneurysmal subarachnoid hemorrhage
   - Panhypopituitarism

2) Congenital abnormalities:
   - Known genetic mutations in growth-hormone releasing hormone (GHRH) receptor, GH gene, GH receptor or pituitary transcription factors
   - Optic nerve hypoplasia/septo-optic dysplasia
   - Empty sella syndrome
   - Ectopic posterior pituitary
   - Pituitary aplasia/hypoplasia
   - Pituitary stalk defect
   - Anencephaly or prosencephaly
   - Other mid-line defects
   - Vascular malformations

3) Pituitary hormones, other than growth hormone (GH):
   - Adrenocorticotropic hormone (ACTH)
   - Antidiuretic hormone (ADH)
   - Follicle stimulating hormone (FSH)
   - Luteinizing hormone (LH)
   - Oxytocin
   - Prolactin
   - Thyroid stimulating hormone (TSH)