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| **Clinical Policy Title:** | somatropin |
| **Policy Number:** | RxA.597 |
| **Drug(s) Applied:** | **Short Acting Growth Hormone:** Genotropin, Humatrope, Norditropin FlexPro, Serostim<br><br>**Long Acting Growth Hormone:** Skytrofa, Ngenla |
| **Original Policy Date:** | 02/07/2020 |
| **Last Review Date:** | 2/28/2024 |
| **Line of Business Policy Applies to:** | All lines of business (except Medicare) |

## Criteria

**I. Initial Approval Criteria**

**A. Growth Hormone Deficiency (GHD) in pediatrics (Genotropin, Humatrope, Norditropin, Skytrofa, Ngenla):**

1. Diagnosis is confirmed by one of the following (a, b, or c);
   a. Height is documented by one of the following (utilizing age and gender growth charts related to height) (i or ii);
      i. Height is greater than 2.0 standard deviations [SD] below midparental height;
      ii. Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender);
   b. Growth velocity is greater than 2 SD below mean for age and gender;
   c. Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age);
2. Patient meets one of the following (a or b):
   a. Patient is male with bone age less than 16 years;
   b. Patient is female with bone age less than 14 years
3. Both of the following (a or b):
   a. Patient has undergone two of the following provocative GH stimulation tests: Arginine, Clonidine, Glucagon, Insulin, Levodopa;
   b. Both tests are less than 10 mcg/L
4. Prescribed by or in consultation with an endocrinologist;

**B. Growth Hormone Deficiency (GHD) in Adults (Genotropin, Humatrope, Norditropin):**

1. Documentation supporting a diagnosis of (a or b):
   a. Childhood-onset GHD;
   b. Adult onset due to hormone deficiency because of hypothalamic-pituitary disease from organic or known causes;
2. Patient meets one of the following (a or b):
   a. Patient has undergone one of the following GH stimulation tests (i, ii or iii):
      i. Insulin tolerance test (ITT) with peak of less than or equal to 5 mcg/L;

ii. Glucagon with peak less than or equal to 3 mcg/L;
iii. Macimorelin with peak less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration;

b. Documented deficiency of three of the following anterior pituitary hormones: Prolactin, Adrenocorticotropic hormone (ACTH), Thyroid stimulating hormone (TSH), and Follicle-stimulating hormone/luteinizing hormone (FSH/LH)

3. Prescribed by or in consultation with an endocrinologist;

**C. Small for gestational age (Genotropin, Humatrope, Norditropin)**

1. Demonstration of catch-up growth failure in the first 24 months of life;
2. One of the following is below the 3rd percentile or 2 SD below population mean for gestational age (a or b):
   a. Birth weight;
   b. Birth length;
3. Prescribed by or in consultation with an endocrinologist;

**D. Turner syndrome (Genotropin, Humatrope, Norditropin):**

1. Patient is female and bone age less than 14 years;
2. Prescribed by or in consultation with an endocrinologist;

**E. Noonan syndrome (Norditropin):**

1. Height is below the 5th percentile on growth charts for age and gender;
2. One of the following (a or b):
   a. Patient is male with bone age less than 16 years;
   b. Patient is female with bone age less than 14 years;
3. Prescribed by or in consultation with an endocrinologist;

**F. Short-Stature Homeobox (SHOX) Gene Deficiency (Humatrope):**

1. One of the following (a or b):
   a. Patient is male with bone age less than 16 years;
   b. Patient is female with bone age less than 14 years;
2. Prescribed by or in consultation with an endocrinologist;

**G. Prader-Willi syndrome (Genotropin, Norditropin):**

**1.** One of the following (a or b):
   a. Patient is male with bone age less than 16 years;
   b. Patient is female with bone age less than 14 years;
2. Prescribed by or in consultation with an endocrinologist;

**H. Wasting or Cachexia in HIV Patients** (Serostim):

1. Diagnosis of HIV infection;
2. Involuntary weight loss of >10% of body weight;
3. One of the following (a or b) unless contraindicated or clinically significant adverse effects are experienced:
   a. If inadequate appetite, failure of megestrol acetate or dronabinol to stimulate appetite;

b. If inadequate intake due to nausea, failure of ≥ 1 preferred agent(s) for nausea;

4. Failure of a therapeutic trial of testosterone in combination with an anabolic steroid in males unless contraindicated or clinically significant adverse effects are experienced;

**Approval Duration (all indications):**
**All Lines of Business (except Medicare):** 12 months

**II. Continued Therapy Approval**

**A. Wasting or Cachexia in HIV Patients:**

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples

**B. All other indications**:

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.
2. Pediatric patients: Increased growth rate by 2 cm over baseline in the first year;
3. Adult patients: Ongoing monitoring by documentation within the past 12 months of an IGF-1/Somatomedin C level.

**Approval Duration (all indications):**
**All Lines of Business (except Medicare):** 12 months

**References**


1. Wilson TA, Rose SR, Cohen P, et al. Update of guidelines for the use of growth hormone in children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. J Pediatr. 2003; 143: 415-421. Available at: https://www.researchgate.net/publication/231586437_Update_of_guidelines_for_the_use_of_growth_hormone_in_children_The_Lawson_Wilkins_Pediatric_Endocrinology_Society_Drug_and_Therapeutics_Committee. Accessed August 30, 2022.
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): 1-28. Available at: https://www.endocrinepractice.org/article/S1530-891X(20)35145-4/fulltext . Accessed August 30, 2022.
3. 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. Available at: https://pubmed.ncbi.nlm.nih.gov/21602453/. Accessed August 31, 2022.
4. Nemecheck PM, Polsky B, Gottlieb MS. Treatment guidelines for HIV-Associated Wasting. Mayo Clin Proc. 2000; 75: 386-394. Available at: https://pubmed.ncbi.nlm.nih.gov/10761494/ .Accessed August 31, 2022.
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6. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin- like growth factor-I treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. Horm Res Paediatr 2016; 86:361-397. Available at: https://pubmed.ncbi.nlm.nih.gov/27884013/ .Accessed August 31, 2022.

7. National Institute for Health and Care Excellence. Human growth hormone (somatropin) for treatment of growth failure in children: technology appraisal guidance; May 2010. Available at: https://www.nice.org.uk/guidance/ta188. Accessed August 31, 2022.

| Review/Revision History | Review/Revision Date | P&T Approval Date |
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| Policy was established. | 05/2018 | 02/07/2020 |
| Policy was reviewed:<br>1. "Gastroenterologist" was added to I.B.3 for SBS.<br>2. This statement was added: "Isolated growth hormone deficiency (GHD) is defined by growth failure in combination with retarded bone age, low serum insulin-like growth factor-1, and insufficient GH peaks in two independent GH stimulation tests." | 12/17/2020 | |
| Policy was reviewed:<br>1. Initial Approval Criteria I.A.1.b ISS SD value was changed from 2.25 to 2.<br>2. Initial Approval Criteria I.A.8 was updated to include "Unless treating CKD" at the beginning of the clause.<br>3. Initial Approval Criteria I.B.1.a.1 was updated to remove "retarded bone age".<br>4. Initial approval criteria I.A.4. was updated to include weight criteria for Skytrofa.<br>5. Initial Approval Criteria I.B.6 & I.C.8 was updated to include maximum dose.<br>6. Initial Approval Criteria I.C.7 was changed from failure of preferred products to "Request must be for Serostim".<br>7. Continued Approval Criteria II.A.2.b was updated to | 11/03/2021 | 12/07/2021 |

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| change SD value from 2.25 to 2.<br>8. Continued approval criteria II.A.3 was updated to include "For Skytrofa™, member is responding positively to therapy as evidenced by..."<br>9. Therapeutic Alternatives was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..".<br>10. References were reviewed and updated. | | |
| Policy was reviewed:<br>1. References were reviewed and updated. | 08/31/2022 | 10/19/2022 |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |
| Policy was reviewed. | 2/28/2024 | 2/28/2024 |