

<b>Clinical Policy Title:</b>	Growth hormones
<b>Policy Number:</b>	RxA.597
<b>Drug(s) Applied:</b>	<b>Short-Acting Growth Hormone:</b> Omnitrope, Norditropin FlexPro, Serostim  <b>Long-Acting Growth Hormone:</b> Skytrofa, Ngenla
<b>Original Policy Date:</b>	02/07/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Growth Hormone Deficiency (GHD) in Pediatrics ( Omnitrope, Norditropin, Skytrofa, Ngenla) (must meet all):

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 and 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.

#### B. Growth Hormone Deficiency (GHD) in Adults ( Omnitrope, Norditropin, Skytrofa) (must meet all):

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;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

- 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, Adrenocorticotrophic hormone (ACTH), Thyroid stimulating hormone (TSH), and Follicle-stimulating hormone/luteinizing hormone (FSH/LH).

**C. Small for gestational age** (Omnitrope, Norditropin) (must meet all):

- 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.

**D. Turner syndrome** (Omnitrope, Norditropin) (must meet all):

- 1. Patient is female and bone age less than 14 years.

**E. Noonan syndrome** (Norditropin) (must meet all):

- 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.

**F. Prader-Willi syndrome** (Omnitrope, Norditropin) (must meet all):

- 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.

**G. Wasting or Cachexia in HIV Patients** (Serostim) (must meet all):

- 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  $\geq 1$  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;

**H. Idiopathic Short Stature** (Omnitrope, Norditropin) (must meet all):

- 1. Diagnosis of idiopathic short stature;
- 2. Patient's meets both of the following (a and b):
  - a. Height > 2.25 SD below the mean for age and sex;
  - b. Not likely to attain adult height in the normal range;

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

**II. Continued Therapy Approval**

**A. All Indications:**

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met the initial approval criteria.

**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](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 March 19, 2025.
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](https://www.endocrinepractice.org/article/S1530-891X(20)35145-4/fulltext) . Accessed March 19, 2025.
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 March 19, 2025.
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 March 19, 2025.
5. Polsky B, Kotler D, Steinhart C. Treatment guidelines for HIV-associated wasting. HIV Clin Trials 2004;5(1):50-61. Available at: <https://pubmed.ncbi.nlm.nih.gov/10761494/> . Accessed March 19, 2025.
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 March 19, 2025.
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 March 19, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established.	05/2018	02/07/2020
Policy was reviewed: 1. "Gastroenterologist" was	12/17/2020	

<p>added to I.B.3 for SBS.</p> <p>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.”</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.1.b ISS SD value was changed from 2.25 to 2.</li> <li>2. Initial Approval Criteria I.A.8 was updated to include “Unless treating CKD” at the beginning of the clause.</li> <li>3. Initial Approval Criteria I.B.1.a.1 was updated to remove “retarded bone age”.</li> <li>4. Initial approval criteria I.A.4. was updated to include weight criteria for Skytrofa.</li> <li>5. Initial Approval Criteria I.B.6 &amp; I.C.8 was updated to include maximum dose.</li> <li>6. Initial Approval Criteria I.C.7 was changed from failure of preferred products to “Request must be for Serostim”.</li> <li>7. Continued Approval Criteria II.A.2.b was updated to change SD value from 2.25 to 2.</li> <li>8. Continued approval criteria II.A.3 was updated to include "For Skytrofa™, member is responding positively to therapy as evidenced by..."</li> <li>9. Therapeutic Alternatives was rephrased to "Below are</li> </ol>	<p>11/03/2021</p>	<p>12/07/2021</p>

<p>suggested therapeutic alternatives based on clinical guidance..".</p> <p>10. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <p>1. References were reviewed and updated.</p>	08/31/2022	10/19/2022
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed.</p>	2/28/2024	2/28/2024
<p>Policy was reviewed:</p> <p>2. Updated to include new indication, Idiopathic Short Stature.</p> <p>3. References were reviewed and updated.</p>	03/19/2025	04/10/2025
<p>Policy was reviewed:</p> <p>1. Skytrofa now indicated for Growth Hormone Deficiency (GHD) in Adults.</p> <p>2. Removed Genotropin and Humatrope from policy</p> <p>3. Added Omnitrope</p>	11/01/2025	12/11/2025