Growth Hormone

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Growth Hormone drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. The criteria will require the use one of the health plan's preferred growth hormones, Norditropin and Omnitrope, prior to the use of non-preferred growth hormones unless requesting Nutropin/Nutropin AQ or Humatrope for chronic kidney disease (CKD), or short stature homeobox-containing gene (SHOX) deficiency, respectively. Serostim is excluded from preferred growth hormone requirement. Growth hormone therapy must be prescribed by or in consultation with a specialist (endocrinologist, geneticist, pediatric nephrologist, gastroenterologist/nutritional support specialist, or an infectious disease specialist) and the patient must not have an active malignancy or history of malignancy in the past 12 months.

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
  - Idiopathic short stature (ISS)
- Adults with childhood-onset or adult-onset GH deficiency
- Short bowel syndrome (SBS)
- Human immunodeficiency virus (HIV)-associated wasting/cachexia

Growth Hormone	Generic Name	FDA Approved Indications
Genotropin®	somatropin	Pediatric GHD, adult GHD, TS, ISS, SGA, PWS
Humatrope®	somatropin	Pediatric GHD, adult GHD, TS, ISS, SGA, SHOXD
Ngenla™	somatrogon-ghla	Pediatric GHD (3 years and older)
Norditropin®	somatropin	Pediatric GHD, adult GHD, TS, ISS, SGA, PWS, NS
Nutropin/Nutropin AQ®	somatropin	Pediatric GHD, adult GHD, TS, ISS, CKD
Omnitrope®	somatropin	Pediatric GHD, adult GHD, TS, ISS, SGA, PWS
Saizen®	somatropin	Pediatric GHD, adult GHD
Serostim®	somatropin	HIV-associated wasting/cachexia
Skytrofa®	lonapegsomatropin-tcgd	Pediatric GHD (1 year and older who weight at least 11.5kg), adult GHD
Sogroya®	somapacitan-beco	Pediatric GHD, ISS, NS, SGA (2.5 years and older), adult GHD
Zomacton®	somatropin	Pediatric GHD, SGA, adult GHD, SHOXD, TS, ISS

POLICY

REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review for both initial and continuation of therapy requests (where applicable):

- Medical records supporting the diagnosis of neonatal growth hormone (GH) deficiency
- Pretreatment growth hormone provocative test result(s) (laboratory report or medical record documentation)
- Growth Chart
- Pretreatment and/or current IGF-1 level (laboratory report or medical record documentation)*
- The following laboratory test reports must be provided:
    - Diagnostic karyotype results in Turner syndrome
    - Diagnostic genetic test results in Prader-Willi syndrome
    - Diagnostic molecular or genetic test results in SHOX deficiency
- The following information must be provided for all continuation of therapy requests:
    - Total duration of treatment (approximate duration is acceptable)
    - Date of last dose administered
    - Approving health plan/pharmacy benefit manager
    - Date of prior authorization/approval
    - Prior authorization approval letter
- Body mass index (BMI) documentation may be required for review of adult growth hormone deficiency

* IGF-1 levels vary based on the laboratory performing the analysis. Laboratory-specific values must be provided to determine whether the value is within the normal range.

PRESCRIBER SPECIALTIES

For all diagnoses excluding HIV-associated wasting/cachexia, therapy must be prescribed by or in consultation with any of the following specialists:

- Endocrinologist
- Pediatric endocrinologist
- Geneticist
- Pediatric nephrologist (CKD only)
- Gastroenterologist/Nutritional support specialist (SBS only)

INITIAL CRITERIA FOR APPROVAL

* The criteria will require the use one of the health plan's preferred growth hormones, Norditropin and Omnitrope, prior to the use of non-preferred growth hormones unless requesting Nutropin/Nutropin AQ for chronic kidney disease (CKD). Serostim is excluded from preferred growth hormone requirement. Sogroya will only be covered for growth hormone deficiency in adults and pediatric patients 2.5 years of age and older when criteria are met. Skytrofa will only be covered for growth hormone deficiency in adults and pediatric patients 1 year of age and older when criteria are met. Ngenla will only be covered for pediatric growth hormone deficiency in patients 3 years of age and older when criteria are met. Ngenla, Skytrofa and Sogroya will not be covered for any other indication.

I. Growth hormone may be considered **medically necessary** for the treatment of pediatric growth hormone deficiency when the following criteria are met:
   a. Patient is a neonate, unless the requested drug is Ngenla, Skytrofa or Sogroya, or was diagnosed with GH deficiency as a neonate. Medical records must be available to support the diagnosis of neonatal GH deficiency (e.g., hypoglycemia with random GH level, evidence of multiple pituitary hormone deficiency, chart notes, or magnetic resonance imaging [MRI] results).

   OR

   b. Patient meets ALL of the following:
      i. Patient has EITHER:
         1. Two pretreatment pharmacologic provocative GH tests with both results demonstrating a peak GH level < 10 ng/mL, OR
         2. A documented pituitary or CNS disorder (refer to Appendix A) and a pretreatment IGF-1 level > 2 standard deviations (SD) below the mean
      ii. For patients < 2.5 years of age at initiation of treatment:
         1. Pretreatment height is > 2 SD below the mean and growth velocity is slow
      iii. For patients ≥ 2.5 years of age at initiation of treatment:
         1. Pretreatment height is > 2 SD below the mean and 1-year height velocity is >1 SD below the mean, OR
         2. Pretreatment 1-year height velocity is > 2 SD below the mean.
      iv. Epiphyses are open

   Approval is for **12 months.**

II. Growth hormone may be considered **medically necessary** for the treatment of Turner Syndrome when ALL of the following criteria are met:
   a. Diagnosis was confirmed by karyotyping
   b. Patient's pretreatment height is less than the 5th percentile for age
   c. Epiphyses are open

   Approval is for **12 months.**

III. Growth hormone may be considered **medically necessary** for the treatment of Noonan Syndrome when ALL of the following criteria are met:
   a. Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean OR pretreatment 1-year height velocity is > 2 SD below the mean
   b. Epiphyses are open

   Approval is for **12 months.**

IV. Growth hormone may be considered **medically necessary** for the treatment of growth failure associated with chronic kidney disease when ALL of the following criteria are met:
   a. For patients < 2.5 years of age at initiation of treatment:
      i. Pretreatment height is > 2 SD below the mean and growth velocity is slow.
   b. For patients ≥ 2.5 years of age at initiation of treatment
      i. Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean, OR
      ii. Pretreatment 1-year height velocity is > 2 SD below the mean
   c. Epiphyses are open

   Approval is for **12 months.**

V. Growth hormone may be considered **medically necessary** for the treatment of short children born small for gestational age when ALL of the following criteria are met:
   a. Patient meets at least one of the following:
      i. Birth weight < 2500 g at gestational age > 37 weeks
      ii. Birth weight or length less than 3rd percentile for gestational age
      iii. Birth weight or length ≥ 2 SD below the mean for gestational age
   b. Pretreatment age is ≥ 2 years
   c. Patient failed to manifest catch-up growth by age 2 (i.e., pretreatment height is > 2 SD below the mean)
   d. Epiphyses are open

   Approval is for **12 months.**

VI. Growth hormone may be considered **medically necessary** for the treatment of Prader-Willi Syndrome when the following criteria are met:
   a. The diagnosis of Prader-Willi syndrome was confirmed by genetic testing demonstrating any of the following:
      i. Deletion in the chromosomal 15q11.2-q13 region
      ii. Maternal uniparental disomy in chromosome 15
      iii. Imprinting defects, translocations, or inversions involving chromosome 15

   Approval is for **12 months.**

VII. Growth hormone may be considered **medically necessary** for the treatment of Idiopathic Short Stature when ALL of the following criteria are met:
   a. Pretreatment height is > 2.25 SD below the mean
   b. Predicted adult height is < 5’3” for boys and < 4’11” for girls
   c. Pediatric growth hormone (GH) deficiency has been ruled out with a provocative GH test (peak GH level ≥ 10 ng/mL)
   d. Epiphyses are open

Approval is for **12 months.**

VIII. Growth hormone may be considered **medically necessary** for the treatment of Short Stature Homeobox-Containing Gene (SHOX) deficiency when ALL of the following criteria are met:
   a. The diagnosis of SHOX deficiency was confirmed by molecular or genetic analyses
   b. Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean OR pretreatment 1-year height velocity is > 2 SD below the mean
   c. Epiphyses are open

   Approval is for **12 months.**

IX. Growth hormone may be considered **medically necessary** for the treatment of adult growth hormone deficiency when ANY of the following criteria are met:
   a. The patient meets both of the following:
      i. The patient has had 2 pretreatment pharmacologic provocative GH tests and both results demonstrated deficient GH responses defined as the following:
         1. Insulin tolerance test (ITT) with a peak GH level ≤ 5 ng/mL
         2. Macrilen with a peak GH level less than 2.8 ng/mL
         3. Glucagon stimulation test with a peak GH level ≤ 3 ng/mL in patients with a body mass index (BMI) less than or equal to 30 kg/m^2 and a high pretest probability (e.g., acquired structural abnormalities) OR a BMI less than 25 kg/m^2
         4. Glucagon stimulation test with a peak GH level ≤ 1 ng/mL in patients with a BMI ≥ 25 kg/m^2 and a low pretest probability (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m^2
      ii. The patient has a low pre-treatment IGF-1 (between 0 to 2 SD below the mean for age and gender)
   b. The patient meets both of the following:
      i. The patient has had 1 pretreatment pharmacologic provocative GH test that demonstrated deficient GH responses defined as one of the following:
         1. Insulin tolerance test (ITT) with a peak GH level ≤ 5 ng/mL
         2. Macrilen with a peak GH level less than 2.8 ng/mL
         3. Glucagon stimulation test with a peak GH level ≤ 3 ng/mL in patients with a body mass index (BMI) less than or equal to 30 kg/m^2 and a high pretest probability (e.g., acquired structural abnormalities) OR a BMI less than 25 kg/m^2
         4. Glucagon stimulation test with a peak GH level ≤ 1 ng/mL in patients with a BMI ≥ 25 kg/m^2 and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m^2
      ii. The patient has a pretreatment IGF-1 level that is more than 2 SD below the mean for age and gender
   c. The patient has organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with ≥ 3 documented pituitary hormone deficiencies [refer to Appendix B] and a low pre-treatment IGF-1 more than 2 standard deviations below the mean for age and gender
   d. The patient has documented genetic or structural hypothalamic-pituitary defects (refer to Appendix A)
   e. The patient has childhood-onset GH deficiency and a documented congenital abnormality of the CNS, hypothalamus or pituitary (refer to Appendix A)

   Approval is for **12 months.**

X. Growth hormone may be considered **medically necessary** for the treatment of HIV-Associated Wasting/Cachexia when ALL of the following criteria are met:
   a. Patient is diagnosed with HIV-associated wasting/cachexia
   b. Patient has tried and had a suboptimal response to alternative therapies (e.g., cyproheptadine, dronabinol, megestrol acetate or testosterone if hypogonadal) unless the patient has a contraindication or intolerance to alternative therapies
   c. Patient is currently on antiretroviral therapy
   d. Patient meets any of the following criteria:
      i. Patient has a documented unintentional weight loss of ≥5% over 6 months
      ii. Patient has a documented unintentional weight loss of ≥10% over 12 months
      Patient has a body mass index (BMI) of <20kg/m^2 prior to initiating therapy with growth hormone (see Appendix D).

   Approval is for **12 weeks.**

XI. Growth hormone may be considered **medically necessary** for the treatment of Short Bowel Syndrome (SBS) when ALL of the following criteria are met:
   a. Patient is dependent on intravenous parenteral nutrition for nutritional support
   b. GH will be used in conjunction with optimal management of SBS
   c. Patient has not previously received GH therapy for more than 8 weeks

   Approval is for **8 weeks.**

CONTINUATION OF THERAPY

I. The continuation of growth hormone therapy may be considered **medically necessary** for the treatment of pediatric growth hormone deficiency, Turner Syndrome, Noonan Syndrome, CKD, SGA, ISS, and SHOX deficiency when ALL of the following criteria are met:
   i. Epiphyses are open (confirmed by X-ray or X-ray is not available)
   ii. Patient's growth rate is > 2 cm/year unless there is documented clinical reason for lack of efficacy (e.g., on treatment less than 1 year, nearing adult final height/late stages of puberty)

   Approval is for **12 months.**

II. The continuation of growth hormone therapy may be considered **medically necessary** for the treatment of Prader-Willi Syndrome when ALL body composition and psychomotor function have improved or stabilized in response to GH therapy

   Approval is for **12 months.**

III. The continuation of growth hormone therapy may be considered **medically necessary** for the treatment of adult growth hormone deficiency when ANY of the following are met:
   a. The patient meets all of the following:
      i. The patient has had 2 pretreatment pharmacologic provocative GH tests and both results demonstrated deficient GH responses defined as the following:
         1. Insulin tolerance test (ITT) or another provocative GH test with a peak GH level ≤ 5 ng/mL
         2. Macrilen with a peak GH level less than 2.8 ng/mL
         3. Glucagon stimulation test with a peak GH level ≤ 3 ng/mL in patients with a body mass index (BMI) less than or equal to 30 kg/m^2 and a high pretest probability (e.g., acquired structural abnormalities) OR a BMI less than 25 kg/m^2

4. Glucagon stimulation test with a peak GH level ≤ 1 ng/mL in patients with a BMI ≥ 25 kg/m^2 and a low pretest probability (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m^2

ii. The patient has a low pre-treatment IGF-1 (between 0 to 2 SD below the mean for age and gender)

iii. Current IGF-1 level is not elevated for age and gender

b. The patient meets all of the following:
   i. The patient has had 1 pretreatment pharmacologic provocative GH test that demonstrated deficient GH responses defined as one of the following:
      1. Insulin tolerance test (ITT) or another provocative GH test with a peak GH level ≤ 5 ng/mL
      2. Macrilen with a peak GH level less than 2.8 ng/mL
      3. Glucagon stimulation test with a peak GH level ≤ 3 ng/mL in patients with a body mass index (BMI) less than or equal to 30 kg/m^2 and a high pretest probability (e.g., acquired structural abnormalities) OR a BMI less than 25 kg/m^2
      4. Glucagon stimulation test with a peak GH level ≤ 1 ng/mL in patients with a BMI ≥ 25 kg/m^2 and a low pretest probability (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m^2
   ii. The patient has a pretreatment IGF-1 level that is more than 2 SD below the mean for age and gender
   iii. Current IGF-1 level is not elevated for age and gender
c. The patient meets both of the following:
   i. The patient has organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with ≥ 3 documented pituitary hormone deficiencies [refer to Appendix B] and a low pre-treatment IGF-1 more than 2 standard deviations below the mean for age and gender
   ii. Current IGF-1 level is not elevated for age and gender
d. The patient has documented genetic or structural hypothalamic-pituitary defects (refer to Appendix A) and current IGF-1 level is not elevated for age and gender
e. The patient has childhood-onset GH deficiency and a documented congenital abnormality of the CNS, hypothalamus or pituitary (refer to Appendix A) and current IGF-1 level is not elevated for age and gender

XII. The continuation of growth hormone therapy may be considered **medically necessary** for the treatment of HIV-Associated Wasting/Cachexia when ALL of the following criteria are met:
   a. Patient is diagnosed with HIV-associated wasting/cachexia
   b. Patient is currently on antiretroviral therapy
   c. Patient has achieved or maintained a documented positive clinical response (e.g. increase in body weight, weight stabilization, or slowing of disease progression).

   Approval is for **12 weeks.**

Other

Growth Hormone Therapy is considered **not medically necessary** for patients who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Quantity Limits Apply

Product	Quantity Limit
Sogroya 5 mg/1.5 mL prefilled pen	4 per 28 days
Sogroya 10 mg/1.5 mL prefilled pen	4 per 28 days
Sogroya 15 mg/1.5 mL prefilled pen	2 per 28 days

APPENDIX

Appendix A: Examples of Hypothalamic/Pituitary/CNS Disorders

1. Congenital genetic abnormalities
    a. Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2)
    b. Growth hormone releasing hormone (GHRH) receptor gene defects
    c. GH secretagogue receptor gene defects
    d. GH gene defects
2. Congenital structural abnormalities
    a. Optic nerve hypoplasia/septo-optic dysplasia
    b. Agenesis of corpus callosum
    c. Empty sella syndrome
    d. Ectopic posterior pituitary
    e. Pituitary aplasia/hypoplasia
    f. Pituitary stalk defect
    g. Holoprosencephaly
    h. Encephalocele
    i. Hydrocephalus
    j. Anencephaly or prosencephaly
    k. Arachnoid cyst
    l. Other mid-line facial defects (e.g., single central incisor, cleft lip/palate)
    m. Vascular malformations
3. Acquired structural abnormalities (or causes of hypothalamic/pituitary damage)
    a. CNS tumors/neoplasms (e.g., craniopharyngioma, glioma/astrocytoma, pituitary adenoma, germinoma)
    b. Cysts (Rathke cleft cyst or arachnoid cleft cyst)
    c. Surgery
    d. Radiation

e. Chemotherapy
f. CNS infections
g. CNS infarction
h. Inflammatory processes (e.g., autoimmune hypophysitis)
i. Infiltrative processes (e.g., sarcoidosis, histiocytosis, hemochromatosis)
j. Head trauma/traumatic brain injury
k. Aneurysmal subarachnoid hemorrhage
l. Perinatal or postnatal trauma
m. Surgery of the pituitary or hypothalamus

Appendix B: Pituitary Hormones (Other than Growth Hormone)

1. Adrenocorticotropic hormone (ACTH)
2. Antidiuretic hormone (ADH)
3. Follicle stimulating hormone (FSH)
4. Luteinizing hormone (LH)
5. Thyroid stimulating hormone (TSH)
6. Prolactin

Appendix C: Requirements for GH-Stimulation Testing in Adults

1. Testing for adult GHD is not required
    a. Three or more pituitary hormone deficiencies and low IGF-1
    b. Congenital structural abnormalities
        i. Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2
        ii. GHRH receptor-gene defects
        iii. GH-gene defects associated with brain structural defects
        iv. Single central incisor
        v. Cleft lip/palate
    c. Acquired causes such as perinatal insults
2. Testing for adult GHD is required
    a. Acquired
        i. Skull-base lesions
        ii. Pituitary adenoma
        iii. Craniopharyngioma
        iv. Rathke's cleft cyst
        v. Meningioma
        vi. Glioma/astrocytoma
        vii. Neoplastic sellar and parasellar lesions
        viii. Chordoma
        ix. Hamartoma
        x. Lymphoma
        xi. Metastases
        xii. Other brain injury
        xiii. Traumatic brain injury
        xiv. Sports-related head trauma
        xv. Blast injury
        xvi. Infiltrative/granulomatous disease
        xvii. Langerhans cell histiocytosis
        xviii. Autoimmune hypophysitis (primary or secondary)
        xix. Sarcoidosis
        xx. Tuberculosis
        xxi. Amyloidosis

b. Surgery to the sella, suprasellar, and parasellar region
c. Cranial irradiation
d. Central nervous system infections (bacteria, viruses, fungi, parasites)
e. Infarction/hemorrhage (e.g., apoplexy, subarachnoid hemorrhage, ischemic stroke, snake bite)
f. Empty sella
g. Hydrocephalus
h. Idiopathic

Appendix D: Calculation of BMI

$$\text{BMI} = \frac{\text{Weight (pounds)} \times 703}{[\text{Height (inches)}]^2} \quad \text{OR} \quad \frac{\text{Weight (kg)}}{[\text{Height (m)}]^2}$$

BMI classification:	Underweight	< 18.5 kg/m^2
	Normal weight	18.5 – 24.9 kg/m^2
	Overweight	25 – 29.9 kg/m^2
	Obesity (class 1)	30 – 34.9 kg/m^2
	Obesity (class 2)	35 – 39.9 kg/m^2
	Extreme obesity (class 3)	≥ 40 kg/m^2

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD-CM diagnostic codes.

REFERENCES

- Genotropin [package insert]. New York, NY: Pfizer Inc.; April 2019.
- Humatrope [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2023.
- Ngenla [package insert]. New York, NY: Pfizer Inc.; June 2023.
- Norditropin [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; April 2020.
- Nutropin AQ [package insert]. South San Francisco, CA: Genentech, Inc.; December 2016.
- Saizen [package insert]. Rockland, MA: EMD Serono Inc.; February 2020.
- Serostim [package insert]. Rockland, MA; EMD Serono, Inc.; June 2019
- Skytrofa (lonapegsomatropin-tcgd). Prescribing information. Princeton, NJ: Ascendis Pharma, Inc; July 2025.
- Sogroya [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; February 2026.
- Zomacton [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; July 2018.
- Omnitrope [package insert]. Princeton, NJ: Sandoz Inc.; June 2019.
- Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed January 5, 2021.
- Nemechek PM, Polsky B, Gottlieb MS. Treatment Guidelines for HIV-Associated Wasting. Mayo Clin Proc. 2000;75:386-394.
- Grinspoon S, Mulligan K for the Department of Health and Human Services Working Group on the Prevention and Treatment of Wasting and Weight Loss. Weight loss and wasting in patients infected with human immunodeficiency virus. Clin Infect Dis. 2003;36(Suppl 2):S69-78.

- Polsky B, Kotler D, Steinhart C. HIV-associated wasting in the HAART era: guidelines for assessment, diagnosis, and treatment. AIDS Patient Care STDS. 2001;15(8):411-23.
- Parekh NR, Steiger E. Criteria for the use of recombinant human growth hormone in short bowel syndrome. Nutrition Clin Prac. 2005;20:503-508.
- Congilio SJ, Stevenson RD, Rogol AD. Apparent growth hormone deficiency in children with cerebral palsy. Dev Med Child Neurol. 1996;38(9):797-804.
- Shim ML, Moshang T, Oppenheim WL, et al. Is treatment with growth hormone effective in children with cerebral palsy? Dev Med Child Neurol. 2004;46(8):569-71.
- Gallagher MP, Levine LS, Oberfield SE. A review of the effects of therapy on growth and bone mineralization in children with congenital adrenal hyperplasia. Growth Horm IGF Res. 2005;15 Suppl A:S26-30.
- Lin-Su K, Vogiatzi MG, Marshall I, et al. Treatment with growth hormone and luteinizing hormone releasing hormone analog improves final adult height in children with congenital adrenal hyperplasia. J Clin Endocrinol Metab. 2005;90:3318-3325.
- Quintos JB, Vogiatzi MG, Harbison MD, et al. Growth hormone therapy alone or in combination with gonadotropin-releasing hormone analog therapy to improve the height deficit in children with congenital adrenal hyperplasia. J Clin Endocrinol Metab. 2001;86(4):1511-1517.
- Hardin DS, Adams-Huet B, Brown D, et al. Growth hormone treatment improves growth and clinical status in prepubertal children with cystic fibrosis: results of a multicenter randomized controlled trial. J Clin Endocrinol Metab. 2006; 91(12):4925-9.
- Hardin DS, Ellis KJ, Dyson M, et al. Growth hormone improves clinical status in prepubertal children with cystic fibrosis: Results of a randomized controlled clinical trial. J Pediatr. 2001;139:636-42.
- Hardin DS, Rice J, Ahn C, et al. Growth hormone treatment enhances nutrition and growth in children with cystic fibrosis receiving enteral nutrition. J Pediatr. 2005;146:324-8.
- Ranke MB, Lindberg A. Growth hormone treatment of short children born small for gestational age or with Silver-Russell syndrome: Results from KIGS (Kabi International Growth Study), including the first report on final height. Acta Paediatr Suppl. 1996;417:18-26.
- Gharib H, Cook DM, Saenger PH, et al. American Association of Clinical Endocrinologists Growth Hormone Task Force. Medical guidelines for clinical practice for growth hormone use in adults and children 2003 Update. Endocr Pract. 2003;9(1):64-76.
- National Institute for Clinical Excellence: Guidance on the use of human growth hormone (somatropin) for the treatment of growth failure in children. May 2010. http://www.nice.org.uk/guidance/ta88. Accessed January 15, 2021.
- 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.
- Franklin SL, Geffner ME. Growth hormone: the expansion of available products and indications. Pediatr Clin North Am. 2011;58:1141-1165.
- 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.
- Allen NG, Bangalore Krishna K, Lee PA. Use of gonadotropin-releasing hormone analogs in children. *Curr Opin Pediatr*. 2021;33(4):442-448.
- Growth Hormone Usage in Short Children: American Association of Clinical Endocrinologists Position Statement. https://www.aace.com/files/position-statements/shortchildren.pdf. Accessed January 15, 2021.
- 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:E1072-E1087.

- Blum WF, Crowe BJ, Quigley CA, et al. Growth hormone is 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 Endocrinol Metab. 2007;92:219-228.
- Blum WF, Ross JL, Zimmermann AG, et al. GH treatment to final height produces similar height gains in patients with SHOX deficiency and Turner syndrome: results of a multicenter trial. *J Clin Endocrinol Metab*. 2013;98(8):E1383-92.
- Cook DM, Yuen KCJ, Biller BMK, Kemp SF, Lee Vance M. 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.
- 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.
- National Institute for Clinical Excellence: Human growth hormone (somatropin) in adults with growth hormone deficiency. August 2003.
- Deal C, Hasselmann C, Pfaffle RW, et al. Associations between pituitary imaging abnormalities and clinical and biochemical phenotypes in children with congenital growth hormone deficiency: data from an international observational study. Horm Res Paediatr. 2013;79:283-292.
- National Heart, Lung, and Blood Institute. Obesity Education Initiative: The practical guide: identification, evaluation, and treatment of overweight and obesity in adults. Bethesda, MD: US Dept of Health and Human Services, National Heart, Lung, and Blood Institute; 2000. NIH Publication No. 00-4084.
- Macrilen [package insert]. Goettingen, Germany: Allphamed Pharbil Arzneimittel GmbH; July 2021.
- Yuen KCJ, Biller BMK, Radovick S, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Growth Hormone Deficiency in Adults and Patients Transitioning from Pediatric to Adult Care. *Endocrine Practice*. 2019;25:1191-1232.
- Wakeling E, Brioude F, Lokulo-Sodipe O, et al. Diagnosis and management of Silver-Russell syndrome: first international consensus statement. Nat Rev Endocrinol. 2017;13:105-124.
- U.S. National Library of Medicine. ClinicalTrials.gov. Trial to Compare the Efficacy and Safety of NNC0195-0092 (Somapacitan) With Placebo and Norditropin FlexPro (Somatropin) in Adults With Growth Hormone Deficiency (REAL 1). https://clinicaltrials.gov/ct2/show/study/NCT02229851. Accessed 09/04/2020.
- Butler MG, Miller JL, Forster JL. Prader-Willi syndrome – clinical genetics, diagnosis and treatment approaches: An update. *Curr Pediatr Rev*. 2019;15(4):207-244.

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