

## Clinical Policy: Human Growth Hormone (Somapacitan, Somatropin)

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[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

The following human growth hormone (hGH) formulations require prior authorization:

- hGH analogs: somapacitan-beco (Sogroya<sup>®</sup>)
- Recombinant hGH (rhGH) formulations: somatropin (Genotropin<sup>®</sup>, Humatrope<sup>®</sup>, Norditropin<sup>®</sup>, Nutropin AQ<sup>®</sup>, Omnitrope<sup>®</sup>, Saizen<sup>®</sup>, Serostim<sup>®</sup>, Zomacton<sup>®</sup>, Zorbtive<sup>®</sup>)

Drugs	Children								Adults		
	GHD	PWS	TS	NS	SHOX	CKD	SGA	ISS	GHD	HIV	SBS
Sogroya									X		
Genotropin	GF	GF	GF				GF	GF	X		
Humatrope	SS/GF		SS/GF		SS/GF		SS/GF	SS/GF	X		
Norditropin	GF	GF	SS	SS			SS	SS	X		
NutropinAQ	GF		GF			GF		GF	X		
Omnitrope	GF	GF	GF				GF	GF	X		
Saizen	GF								X		
Serostim										X	
Zomacton	GF		SS		SS		SS	SS	X		
Zorbtive											X

Abbreviations: CKD: chronic kidney disease, GF: growth failure, GHD: growth hormone deficiency, HIV: human immunodeficiency virus, ISS: idiopathic short stature, NS: Noonan syndrome, PWS: Prader-Willi syndrome, SBS: short bowel syndrome, SGA: small for gestational age, SHOX: short stature homeobox-containing gene, SS: short stature, TS: Turner syndrome

### FDA Approved Indication(s)

#### hGH Analogs:

Sogroya is indicated for:

- Replacement of endogenous GH in adults with GHD

#### rhGH Formulations:

Genotropin is indicated for treatment of:

- Children with GF due to GHD, PWS, SGA, TS, and ISS.
- Adults with either childhood-onset (CO) or adult-onset (AO) GHD.

Humatrope is indicated for treatment of:

- Children with SS or GF associated with GHD, TS, ISS, SHOX deficiency, and failure to catch up in height after SGA birth.
- Adults with either CO or AO GHD.

## CLINICAL POLICY

### Human Growth Hormone

#### Norditropin FlexPro is indicated for the treatment of:

- Children with GF due to GHD, SS associated with NS, SS associated with TS, SS born SGA with no catch-up growth by age 2 to 4 years, ISS, and GF due to PWS.
- Adults with either CO or AO GHD.

#### Nutropin AQ is indicated for the treatment of:

- Children with GF due to GHD, ISS, TS, and CKD up to the time of renal transplantation.
- Adults with either CO or AO GHD.

#### Omnitrope is indicated for the treatment of:

- Children with GF due to GHD, PWS, SGA, TS, and ISS.
- Adults with either CO or AO GHD.

#### Saizen is indicated for:

- Children with GF due to GHD.
- Adults with either CO or AO GHD.

#### Serostim is indicated for treatment of:

- HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.

#### Zomacton is indicated for:

- Treatment of pediatric patients who have GF due to inadequate secretion of normal endogenous GH, SS associated with TS, ISS, SS or GF in SHOX deficiency, and SS born SGA with no catch-up growth by 2 years to 4 years.
- Replacement of endogenous GH in adults with GHD.

#### Zorbtive is indicate for treatment of:

- SBS in adult patients receiving specialized nutritional support.

#### Policy/Criteria

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

#### Index

##### I. Initial Approval Criteria

- Growth Hormone Deficiency with Neonatal Hypoglycemia (off-label)
- Growth Hormone Deficiency with Short Stature/Growth Failure - Children (*open epiphyses*)
- Genetic Disorders with Short Stature/Growth Failure - Children
- Chronic Kidney Disease with Growth Failure - Children
- Born Small for Gestational Age with Short Stature/Growth Failure - Children

## CLINICAL POLICY

### Human Growth Hormone

- F. Growth Hormone Deficiency - Adults and Transition Patients (*closed epiphyses*)
- G. Short Bowel Syndrome - Adults
- H. HIV-Associated Wasting/Cachexia - Adults
- I. Other diagnoses/indications
- II. Continuing Approval Criteria
  - A. All Pediatric Indications (*open epiphyses*)
  - B. Growth Hormone Deficiency - Adults and Transition Patients (*closed epiphyses*)
  - C. Short Bowel Syndrome - Adults
  - D. HIV-Associated Wasting/Cachexia - Adults
  - E. Other diagnoses/indications
- III. Diagnoses/Indications for which coverage is NOT authorized:
- IV. Appendices
- V. Dosage and Administration
- VI. Product Availability
- VII. References

It is the policy of Louisiana Healthcare Connections that Sogroya and somatropin are medically necessary when the following criteria are met:

- I. Initial Approval Criteria
  - A. Growth Hormone Deficiency with Neonatal Hypoglycemia (off-label) (must meet all):
    - 1. Diagnosis of neonatal hypoglycemia due to GHD;
    - 2. Request is for a somatropin formulation;
    - 3. Prescribed by or in consultation with a pediatric endocrinologist;
    - 4. Age < 1 month;
    - 5. Serum GH concentration  $\leq 5$   $\mu\text{g/L}$ ;
    - 6. Member meets (a or b):
      - a. Imaging shows hypothalamic-pituitary abnormality;
      - b. Deficiency of  $\geq 1$  anterior pituitary hormone other than GH (e.g., ACTH, TSH, LH, FSH, prolactin);
    - 7. The requested product is not prescribed concurrently with Increlex<sup>®</sup> (mecasermin);
    - 8. If request is NOT for Zomacton, Zomacton product excipients are contraindicated or member has experienced a clinically significant adverse effect to Zomacton;
    - 9. Dose does not exceed 0.30 mg/kg per week.

Approval duration: 12 months
  - B. Growth Hormone Deficiency with Short Stature/Growth Failure - Children (*open epiphyses*) (must meet all):
    - 1. Diagnosis of GHD;
    - 2. Request is for a somatropin formulation;
    - 3. Prescribed by or in consultation with a pediatric endocrinologist;
    - 4. Age < 18 years;

## CLINICAL POLICY

### Human Growth Hormone

5. If age > 10 years, open epiphysis on x-ray;
  6. Member meets (a or b):
    - a. Low insulin-like growth factor (IGF)-I serum level;
    - b. Low insulin-like growth factor binding protein (IGFBP)-3 serum level;
  7. Member meets (a, b, c, d, or e):
    - a. Two GH stimulation tests with peak serum levels  $\leq 10$   $\mu\text{g/mL}$  (e.g., stimulants: arginine, clonidine, glucagon);
    - b. Deficiency of  $\geq 3$  pituitary hormones (i.e., ACTH, TSH, LH, FSH, prolactin);
    - c. Surgery or radiotherapy to the hypothalamic-pituitary region;
    - d. Imaging shows hypothalamic-pituitary abnormality;
    - e. GHD-specific mutation (e.g., POU1F1, PROP1, LHX3, LHX4, HESX1, OTX2, TBX19, SOX2, SOX3, GLI2, GHRHR, GH1);
  8. Member meets (a or b):
    - a. SS: height is > 2 SD below the mean for age and sex (SD, height, date, and age in months within the last 90 days are required);
    - b. GF: one of the following (i, ii, or iii):
      - i. Height deceleration across two growth chart percentiles representing > 1 SD below the mean for age and sex (SD and 2 heights, dates, and ages in months at least 6 months apart within the last year are required);
      - ii. Growth velocity > 2 SD below the mean for age and sex over 1 year (SD and 2 heights, dates, and ages in months at least 1 year apart within the last year are required);
      - iii. Growth velocity > 1.5 SD below the mean for age and sex sustained over 2 years (SD and 2 heights, dates, and ages in months at least 2 years apart within the last two years are required);
  9. The requested product is not prescribed concurrently with Increlex (mecasermin);
  10. If request is NOT for Zomacton, Zomacton product excipients are contraindicated or member has experienced a clinically significant adverse effect to Zomacton;
  11. Dose does not exceed 0.30 mg/kg per week.  
Approval duration: 12 months
- C. Genetic Disorders with Short Stature/Growth Failure - Children (must meet all):
1. Diagnosis of PWS, TS, NS, or SHOX deficiency confirmed by a genetic test;
  2. Request is for a somatotropin formulation;
  3. Prescribed by or in consultation with a pediatric endocrinologist;
  4. Age < 18 years;
  5. If age > 10 years, open epiphysis on x-ray;
  6. Member meets (a or b):
    - a. SS: height is > 2 SD below the mean for age and sex (> 1.5 SD if TS) (SD, height, date, and age in months within the last 90 days are required);
    - b. GF: one of the following (i, ii, or iii):

## CLINICAL POLICY

### Human Growth Hormone

- i. Height deceleration across two growth chart percentiles representing > 1 SD below the mean for age and sex (SD and 2 heights, dates, and ages in months at least 6 months apart within the last year are required);
  - ii. Growth velocity > 2 SD below the mean for age and sex over 1 year (SD and 2 heights, dates, and ages in months at least 1 year apart within the last year are required);
  - iii. Growth velocity > 1.5 SD below the mean for age and sex sustained over 2 years (SD and 2 heights, dates, and ages in months at least 2 years apart within the last two years are required);
7. The requested product is not prescribed concurrently with Increlex (mecasermin);
  8. If request is NOT for Zomacton, Zomacton product excipients are contraindicated or member has experienced a clinically significant adverse effect to Zomacton;
  9. Request meets one of the following (a, b, or c):
    - a. PWS: Dose does not exceed 0.24 mg/kg per week;
    - b. TS, NS: Dose does not exceed 0.5 mg/kg per week;
    - c. SHOX deficiency: Dose does not exceed 0.35 mg/kg per week.

Approval duration: 12 months

#### D. Chronic Kidney Disease with Growth Failure – Children (must meet all):

1. Diagnosis of CKD;
2. Request is for a somatotropin formulation;
3. Prescribed by or in consultation with a pediatric endocrinologist or nephrologist;
4. Age < 18 years;
5. If age > 10 years, open epiphysis on x-ray;
6. Member meets (a, b, c, or d):
  - a. GFR < 60 mL/min per 1.73 m<sup>2</sup> for ≥ 3 months;
  - b. Dialysis dependent;
  - c. Diagnosis of nephropathic cystinosis;
  - d. History of kidney transplant ≥ 1 year ago;
7. Member meets (a or b):
  - a. SS: height is > 2 SD below the mean for age and sex (SD, height, date, and age in months within the last 90 days are required);
  - b. GF: one of the following (i, ii, or iii):
    - i. Height deceleration across two growth chart percentiles representing > 1 SD below the mean for age and sex (SD and 2 heights, dates, and ages in months at least 6 months apart within the last year are required);
    - ii. Growth velocity > 2 SD below the mean for age and sex over 1 year (SD and 2 heights, dates, and ages in months at least 1 year apart within the last year are required);
    - iii. Growth velocity > 1.5 SD below the mean for age and sex sustained over 2 years (SD and 2 heights, dates, and ages in months at least 2 years apart within the last two years are required);

## CLINICAL POLICY

### Human Growth Hormone

8. The requested product is not prescribed concurrently with Increlex (mecasermin);
  9. If request is NOT for Zomacton, Zomacton product excipients are contraindicated or member has experienced a clinically significant adverse effect to Zomacton;
  10. Dose does not exceed 0.35 mg/kg per week.  
Approval duration: 12 months
- E. Born Small for Gestational Age with Short Stature/Growth Failure - Children (must meet all):
1. Diagnosis of SGA;
  2. Request is for a somatropin formulation;
  3. Prescribed by or in consultation with a pediatric endocrinologist;
  4. Age  $\geq$  2 years and  $<$  18 years;
  5. If age  $>$  10 years, open epiphysis on x-ray;
  6. Member meets (a and b):
    - a. Birth weight or length  $>$  2 SD below the mean for gestational age (SD, birth weight or length, and gestational age are required);
    - b. Current height  $>$  2 SD below the mean for age and sex measured within the last year at  $\geq$  2 years of age (SD, height, date, and age in months are required);
  7. The requested product is not prescribed concurrently with Increlex (mecasermin);
  8. If request is NOT for Zomacton, Zomacton product excipients are contraindicated or member has experienced a clinically significant adverse effect to Zomacton;
  9. Dose does not exceed 0.48 mg/kg per week.  
Approval duration: 12 months
- F. Growth Hormone Deficiency – Adults and Transition Patients (closed epiphyses) (must meet all):
1. Diagnosis of GHD;
  2. Prescribed by or in consultation with an endocrinologist;
  3. Age  $\geq$  18 years OR closed epiphysis on x-ray;
  4. Member has NOT received somatropin therapy for  $\geq$  1 month prior to GH/IGF-I testing as outlined below;
  5. Member meets (a, b, or c):
    - a. Two fasting a.m. GH stimulation tests with peak serum levels  $\leq$  5  $\mu$ g/mL (accepted stimulants: Macrilen<sup>TM</sup> [macimorelin] or combination of 2 stimulants such as arginine + glucagon);
    - b. Both of the following (i and ii):
      - i. One fasting a.m. GH stimulation test with peak serum level  $\leq$  5  $\mu$ g/ml (accepted stimulants: Macrilen [macimorelin] or combination of 2 stimulants such as arginine + glucagon);
      - ii. One low IGF-I serum level;

## CLINICAL POLICY

### Human Growth Hormone

- c. One low IGF-I serum level and (i, ii, or iii):
  - i. Imaging shows hypothalamic-pituitary abnormality;
  - ii. Deficiency of  $\geq 3$  pituitary hormones (i.e., ACTH, TSH, LH, FSH, prolactin);
  - iii. GHD-specific mutation (e.g., POU1F1, PROP1, LHX3, LHX4, HESX1, OTX2, TBX19, SOX2, SOX3, GLI2, GHRHR, GH1);
6. The requested product is not prescribed concurrently with Increlex (mecasermin);
7. If request is NOT for Zomacton, Zomacton product excipients are contraindicated or member has experienced a clinically significant adverse effect to Zomacton;
8. Dose does not exceed one of the following (a or b):
  - a. For Sogroya: 8 mg once weekly;
  - b. For somatropin formulations: 0.4 mg/day (may adjust by up to 0.2 mg/day every 4 weeks to maintain normal IGF-1 serum levels; doses  $> 1.6$  mg/day would be uncommon).

Approval duration: 6 months

#### G. Short Bowel Syndrome (must meet all):

1. Diagnosis of SBS;
2. Request is for a somatropin formulation;
3. Prescribed by or in consultation with a gastroenterologist;
4. Age  $\geq 18$  years;
5. Patient is dependent upon and receiving intravenous nutrition;
6. If request is NOT for Zomacton, Zomacton product excipients are contraindicated or member has experienced a clinically significant adverse effect to Zomacton;
7. Dose does not exceed 8 mg per day.

Approval duration: up to 4 weeks total

#### H. HIV-Associated Wasting or Cachexia (must meet all):

1. Diagnosis of HIV;
2. Request is for a somatropin formulation;
3. Prescribed by or in consultation with a physician specializing in HIV management;
4. Age  $\geq 18$  years;
5. Unintentional weight loss of  $\geq 10\%$  in the last 12 months occurring while on antiretroviral therapy;
6. Failure of at least 2 pharmacologic therapies from two separate drug classes (Appendix B) unless contraindicated or clinically adverse effects are experienced;
7. If request is NOT for Zomacton, Zomacton product excipients are contraindicated or member has experienced a clinically significant adverse effect to Zomacton;
8. Prescribed dose does not exceed 6 mg per day.

Approval duration: 6 months

## CLINICAL POLICY

### Human Growth Hormone

#### I. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

#### II. Continued Therapy

##### A. All Pediatric Indications (open epiphyses) (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Age < 18 years OR open epiphysis on x-ray;
3. Member meets (a or b):
  - a. For diagnosis of neonatal hypoglycemia, when member has received somatropin therapy for  $\geq 2$  years, member's height has increased  $\geq 2$  cm in the last year as documented by 2 height measurements taken no more than 1 year apart (dates and height measurements required);
  - b. For all other pediatric diagnoses, member's height has increased  $\geq 2$  cm in the last year as documented by 2 height measurements taken no more than 1 year apart (dates and height measurements required);
4. If request is for a dose increase, request meets the one of the following (a, b, c, d, or e):
  - a. GHD with or without neonatal hypoglycemia: New dose does not exceed 0.30 mg/kg per week;
  - b. PWS: New dose does not exceed 0.24 mg/kg per week;
  - c. TS, NS: New dose does not exceed 0.5 mg/kg per week;
  - d. SHOX deficiency, CKD: New dose does not exceed 0.35 mg/kg per week;
  - e. Born SGA: New dose does not exceed 0.48 mg/kg per week.

Approval duration: 12 months

##### B. Growth Hormone Deficiency - Adults and Transition Patients (closed epiphyses) (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. For IGF-1 test results and dosing (test conducted within the last 90 days) (a, b, or c):
  - a. Low IGF-1 serum level (i or ii):
    - i. For Sogroya: 8 mg once weekly;
    - ii. For somatropin formulations: If request is for a dose increase, new dose does not exceed an incremental increase of more than 0.2 mg/day and a total dose of 1.6 mg/day;
  - b. Normal IGF-1 serum level: Requested dose is for the same or lower dose;
  - c. Elevated IGF-1 serum level: Requested dose has been titrated downward.

Approval duration: 12 months

##### C. Short Bowel Syndrome - Adults (must meet all):

## CLINICAL POLICY

### Human Growth Hormone

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met all initial approval criteria;
  2. Member is responding positively to therapy;
  3. Member has not received the requested product for  $\geq 4$  weeks;
  4. If request is for a dose increase, new dose does not exceed 8 mg per day.
- Approval duration: up to 4 weeks total

#### D. HIV-Associated Wasting/Cachexia - Adults (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met all initial approval criteria;
  2. Member is responding positively to therapy;
  3. Member has not received  $\geq 12$  months of therapy;
  4. If request is for a dose increase, new dose does not exceed 6 mg per day.
- Approval duration: up to 12 months total

#### E. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.  
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to LA.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized). Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

### III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy –LA.PMN.53 for Medicaid or evidence of coverage documents.
- B. Idiopathic short stature (ISS);
- C. Constitutional delay of growth and puberty (i.e., constitutional growth delay; the member's growth rate is delayed compared to chronological age but appropriate for bone age as determined by x-ray);
- D. Familial (genetic) short stature (i.e., height velocity and bone age, as determined by x-ray, are within the normal range and one or both parents are short);
- E. Adult short stature or altered body habitus associated with antiviral therapy (other than HIV-associated wasting or cachexia);
- F. Obesity treatment or enhancement of body mass/strength for non-medical reasons (e.g., athletic gains).

### IV. Appendices/General Information

#### Appendix A: Abbreviation/Acronym Key

CKD: chronic kidney disease  
FDA: Food and Drug Administration  
GFR: glomerular filtration rate

GH: growth hormone  
GHD: growth hormone deficiency  
HIV: human immunodeficiency virus

## CLINICAL POLICY

### Human Growth Hormone

**IGF-1: insulin-like growth factor-1**  
**IGFBP-3: insulin-like growth factor binding protein-3**  
**ISS: idiopathic short stature**  
**NS: Noonan syndrome**  
**PWS: Prader-Willi syndrome**  
**rhGH: recombinant human growth hormone**

**SBS: short bowel syndrome**  
**SD: standard deviation**  
**SGA: small for gestational age**  
**SHOX: short stature homeobox-containing gene**  
**TS: Turner syndrome**

#### Appendix B: Therapeutic Alternatives

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.*

<u>Drug*</u>	<u>Dosing Regimen</u>	<u>Dose Limit/Maximum Dose</u>
<b><u>Appetite Stimulants</u></b>		
<b><u>megestrol (Megace®), Syndros®)</u></b>	<b><u>400 - 800 mg PO daily (10 – 20 ml/day)</u></b>	<b><u>800 mg/day</u></b>
<b><u>dronabinol (Marinol®)</u></b>	<b><u>2.5 mg PO bid</u></b>	<b><u>20 mg/day</u></b>
<b><u>Testosterone Replacement Products</u></b>		
<b><u>testosterone enanthate or cypionate (various brands)</u></b>	<b><u>50 - 400 mg IM Q2 – 4 wks</u></b>	<b><u>400 mg Q 2 wks</u></b>
<b><u>Androderm® (testosterone transdermal patch)</u></b>	<b><u>2.5 – 7.5 mg patch applied topically QD</u></b>	<b><u>7.5 mg/day</u></b>
<b><u>testosterone transdermal gel (AndroGel®, Testim®)</u></b>	<b><u>5 - 10 gm gel (delivers 50 – 100 mg testosterone) applied topically QD</u></b>	<b><u>10 gm/day gel (100 mg/day testosterone)</u></b>
<b><u>Anabolic Steroids</u></b>		
<b><u>oxandrolone (Oxandrin®)</u></b>	<b><u>2.5 – 20 mg PO /day</u></b>	<b><u>20 mg/day</u></b>
<b><u>Nausea/Vomiting Treatments</u></b>		
<b><u>chlorpromazine</u></b>	<b><u>10 to 25 mg PO q4 to 6 hours prn</u></b>	<b><u>2,000 mg/day</u></b>
<b><u>perphenazine</u></b>	<b><u>8 to 16 mg/day PO in divided doses</u></b>	<b><u>64 mg/day</u></b>
<b><u>prochlorperazine</u></b>	<b><u>5 to 10 mg PO TID or QID</u></b>	<b><u>40 mg/day</u></b>
<b><u>promethazine</u></b>	<b><u>12.5 to 25 mg PO q4 to 6 hours prn</u></b>	<b><u>50 mg/dose; 100 mg/day</u></b>
<b><u>trimethobenzamide</u></b>	<b><u>300 mg PO TID or QID prn</u></b>	<b><u>1,200 mg/day</u></b>

*Therapeutic alternatives are listed as **Brand name®** (generic) when the drug is available by brand name only and generic (**Brand name®**) when the drug is available by both brand and generic.*

*\*Preferred status may be formulary-specific.*

#### Appendix C: Contraindications/Boxed Warnings

## CLINICAL POLICY

### Human Growth Hormone

- **Somatropin contraindications:**
  - Acute critical illness
  - Children with PWS who are severely obese or have severe respiratory impairment (reports of sudden death)
  - Active malignancy
  - Product hypersensitivity
  - Active proliferative or severe non-proliferative diabetic retinopathy
  - Children with closed epiphyses
- **Sogroya contraindications:**
  - Acute critical illness
  - Active malignancy
  - Hypersensitivity to somapacitan-beco or excipients
  - Active proliferative or severe non-proliferative diabetic retinopathy
- **Boxed warning(s): none reported**

#### Appendix D: Short Stature and Growth Failure

- **For SS, the policy follows the World Health Organization (WHO) definition of > 2 SD below the mean for age and sex.<sup>1</sup>**
- **For GF, the policy follows**
  - **Haymond et al (2013) and Rogol et al (2014) for height deceleration across two major percentiles representing a change of > 1 SD corrected for age and sex<sup>2,3</sup> and**
  - **the Growth Hormone Research Society (2000) for height velocity in the absence of SS that would prompt further investigation, namely, a height velocity > 2 SD below the mean over 1 year or > 1.5 SD below the mean sustained over 2 years for age and sex.<sup>4</sup>**
- **The Centers for Disease Control and Prevention (CDC) recommend WHO growth charts for infants and children age 0 to < 2 years and CDC growth charts for children age 2 years to < 20 years in the U.S.<sup>5</sup>**
  - **Based on CDC recommended growth chart data, SD approximations of major height percentiles falling below the mean are listed below:**
    - **2nd percentile: 2 SD below the mean**
    - **5th percentile: 1.5 SD below the mean**
    - **15th percentile: 1 SD below the mean**
    - **30th percentile: 0.5 SD below the mean**
    - **50th percentile: 0 SD mean**
  - **CDC recommended growth charts, data tables, and related information that may be helpful in assessing length, height and growth are available at the following link: <https://www.cdc.gov/growthcharts/index.htm>.**

*1. WHO Child Growth Standards: Length/Height-for-Age, Weight-for-Age, Weight-for-Length, Weight-for-Height and Body Mass Index-for-Age: Methods and Development. Geneva, Switzerland: World Health Organization; 2006. As cited in CDC. Division of Nutrition, Physical Activity, and Obesity. Growth Chart Training: Using the WHO Growth Charts. Page last reviewed April 15, 2015. Available at [https://www.cdc.gov/nccdphp/dnpao/growthcharts/who/using/assessing\\_growth.htm](https://www.cdc.gov/nccdphp/dnpao/growthcharts/who/using/assessing_growth.htm). Accessed May 1, 2020.*

## CLINICAL POLICY

### Human Growth Hormone

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3. Rogol AD, Hayden GF. Etiologies ad early diagnosis of short stature and growth failure in children and adolescents. J Pediatr. 2014 May;164(5 Suppl):S1-14.e6. doi: 10.1016/j.jpeds.2014.02.027.
4. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. JCEM. 2000; 85(11): 3990-3993.
5. Centers for Disease Control and Prevention, National Center for Health Statistics. CDC growth charts: United States. <http://www.cdc.gov/growthcharts/>. Accessed April 22, 2020.

#### V. Dosage and Administration

<u>Drug Name</u>	<u>Indication</u>	<u>Dosing Regimen</u>	<u>Maximum Dose</u>
<i>Pediatric Indications (Subcutaneous administration; weekly doses should be divided)</i>			
<u>Genotropin,</u> <u>Humatrope,</u> <u>Norditropin,</u> <u>Nutropin, Omnitrope,</u> <u>Saizen, Zomacton</u>	<u>GHD</u>	<u>G, O: 0.16 to 0.24</u> <u>mg/kg/week</u> <u>H, Z: 0.18 to 0.30</u> <u>mg/kg/week</u> <u>N: 0.17 to 0.24 mg/kg/week</u> <u>Nu: to 0.30 mg/kg/week</u> <u>S: 0.18 mg/kg/week</u>	<u>See dosing</u> <u>regimens</u>
<u>Genotropin,</u> <u>Norditropin,</u> <u>Omnitrope</u>	<u>PWS</u>	<u>G, N, O: 0.24 mg/kg/week</u>	<u>0.24 mg/kg/week</u>
<u>Genotropin,</u> <u>Humatrope,</u> <u>Norditropin,</u> <u>Omnitrope, Zomacton</u>	<u>SGA</u>	<u>G, O: to 0.48 mg/kg/week</u> <u>H, N, Z: to 0.47 mg/kg/week</u>	<u>0.48 mg/kg/week</u>
<u>Genotropin,</u> <u>Humatrope,</u> <u>Norditropin,</u> <u>Nutropin, Omnitrope,</u> <u>Zomacton</u>	<u>TS</u>	<u>G, O: 0.33 mg/kg/week</u> <u>H, Nu, Z: to 0.375</u> <u>mg/kg/week</u> <u>N: to 0.47 mg/kg/week</u>	<u>See dosing</u> <u>regimens</u>
<u>Genotropin,</u> <u>Humatrope,</u> <u>Norditropin,</u> <u>Nutropin, Omnitrope,</u> <u>Zomacton</u>	<u>ISS</u>	<u>G, O, No: to 0.47</u> <u>mg/kg/week</u> <u>H, Z: to 0.37 mg/kg/week</u> <u>Nu: to 0.30 mg/kg/week</u>	<u>See dosing</u> <u>regimens</u>
<u>Humatrope, Zomacton</u>	<u>SHOX</u>	<u>H, Z: 0.35 mg/kg/week</u>	<u>0.35 mg/kg/week</u>
<u>Norditropin</u>	<u>NS</u>	<u>0.46 mg/kg/week</u>	<u>0.46 mg/kg/week</u>
<u>Nutropin</u>	<u>CKD</u>	<u>0.35 mg/kg/week</u>	<u>0.35 mg/kg/week</u>
<i>Adult Indications (Subcutaneous administration)</i>			
<u>Genotropin,</u> <u>Humatrope,</u> <u>Norditropin,</u> <u>Nutropin, Omnitrope,</u> <u>Saizen, Zomacton</u>	<u>GHD</u>	<u>0.4 mg/day - may adjust by</u> <u>increments up to 0.2 mg/day</u> <u>every 6 weeks to maintain</u> <u>normal IGF-1 serum levels.*</u>	<u>See dosing</u> <u>regimen</u>

**CLINICAL POLICY**  
Human Growth Hormone

<u>Drug Name</u>	<u>Indication</u>	<u>Dosing Regimen</u>	<u>Maximum Dose</u>
		<u>*Dosing regimen from Endocrine Society guidelines (Fleisher, et al., 2016).</u>  <u>Adult GHD dosing should be substantially lower than that prescribed for children. Adult doses beyond 1.6 mg/day would be uncommon.</u>	
<u>Serostim</u>	<u>HIV-associated wasting</u>	<u>0.1 mg/kg QOD or QD to 6 mg QD</u>	<u>6 mg/day up to 24 weeks</u>
<u>Sogroya</u>	<u>GHD</u>	<u>0.5 mg once weekly – increase by increments of 0.5-1.5 mg every 2-4 weeks based on clinical response and serum IGF-1 concentrations</u>	<u>8 mg/week</u>
<u>Zorbtive</u>	<u>SBS</u>	<u>0.1 mg/kg QD to 8 mg QD</u>	<u>8 mg/day up to 4 weeks</u>

Abbreviations: G: genotropin, H: humatrope, N: norditropin, Nu: nutropin, O: omnitrope, S: saizen, Z: zomacton

**VI. Product Availability**

<u>Drug</u>	<u>Availability*</u>
<u>hGH Analogs</u>	
<u>Sogroya</u>	<u>MD pen: 10 mg/1.5 mL</u>
<u>rhGH Formulations</u>	
<u>Genotropin lyophilized powder</u>	<u>MD dual-chamber syringe: 5 mg, 12 mg</u>
<u>Genotropin Miniquick</u>	<u>SD pen cartridge: 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1.0 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg, and 2.0 mg</u>
<u>Humatrope</u>	<u>MD pen cartridge: 6 mg, 12 mg, 24 mg</u> <u>MD vial: 5mg</u>
<u>Norditropin Flexpro</u>	<u>MD pen: 5 mg/1.5 mL, 10 mg/1.5 mL, 15 mg/1.5 mL, 30 mg/3 mL</u>
<u>Nutropin AQ</u>	<u>MD: NuSpin: 5 mg/2 mL, 10 mg/2 mL, 20 mg/2 mL</u> <u>MD pen cartridge: 10 mg/2 mL, 20 mg/2 mL</u>
<u>Omnitrope</u>	<u>MD pen cartridge: 5 mg/1.5 mL, 10 mg/1.5 mL</u> <u>MD vial: 5.8 mg</u>
<u>Saizen</u>	<u>MD pen cartridge: 8.8 mg</u> <u>MD vial: 5 mg, 8.8 mg</u>
<u>Serostim</u>	<u>MD vial: 4 mg</u> <u>SD vial: 5 mg, 6 mg</u>
<u>Zomacton</u>	<u>MD vial: 5 mg, 10 mg</u>

## CLINICAL POLICY

### Human Growth Hormone

Drug	Availability*
Zorbtive	MD vial: 8.8 mg

*SD: single-dose, MD: multidose*

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## CLINICAL POLICY

### Human Growth Hormone

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Reviews, Revisions, and Approvals	Date
Converted corporate to local policy	01.21

#### Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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## CLINICAL POLICY

### Human Growth Hormone

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