Somatropin (Growth Hormone)

Genotropin®, Humatrope®, Norditropin®, Nutropin®, Nutropin AQ®, Nutropin AQ NuSpin®, Omnitrope®, Saizen®, Zomacton®, Zorbtive®

FDA-Labeled Indications:

Medication	Table 1: FDA Labeled Indication									
	GHD*: Children	GHD*: Adult	Growth failure due to Chronic Renal Insufficiency	Growth Failure in Children Born SGA▪	Prader-Willi Syndrome in Children	Turner's Syndrome	Noonan Syndrome	ISS^	¨SHOX Deficiency	Short Bowel Syndrome
Genotropin[1]	×	×		×	×	×		×		
Humatrope[2]	×	×		×		×		×	×	
Norditropin[3]	×	×		×		×	×			
Nutropin[4]	×	×	×			×		×		
Nutropin AQ[4]	×	×	×			×		×		
Nutropin AQ NuSpin[4]	×	×	×			×		×		
Saizen[5]	×	×								
Omnitrope[6]	×	×		×	×	×		×		
Zomacton[7]	×									
Zorbtive[8]										×

*GHD (growth hormone deficiency). ▪SGA (small for gestational age). ^ISS (Idiopathic short stature). ¨ Short Stature Homeobox-Containing gene

Dosage Form/Strength: [1, 2, 3, 4, 5, 6, 7, 8]

- Genotropin: 12mg and 5.8mg powder for Injection
- Genotropin Miniquick: 0.2mg, 0.4mg, 0.6mg, 0.8mg, 1mg, 1.2mg, 1.4mg, 1.6mg, 1.8mg, 2mg powder for injection
- Humatrope: 5mg powder for injection
- Humatrope Cartridge Kit: 6mg, 12mg, 24mg powder for injection
- Norditropin FlexPro Prefilled Pen: 5mg/1.5mL, 10mg/1.5mL, 15mg/1.5mL, 30mg/3mL solution for injection
- Nutropin AQ NuSpin: 10mg, 20mg solution for injection
- Nutropin AQ NuSpin Cartridge: 5mg/2mL solution for injection
- Nutropin AQ Pen Cartridge: 10mg/2mL, 20mg/2mL
- Omnitrope: 5.8mg powder for injection
- Omnitrope: 5mg/1.5mL, 10mg/1.5mL solution for injection
- Saizen: 5mg, 8.8mg powder for injection
- Saizen Click.Easy Cartridge: 8.8mg powder for injection
- Zomacton: 5mg, 10mg powder for injection
- Zorbtive: 8.8mg powder for injection

Growth Chart References:

Refer to the following location for links to the WHO and CDC growth charts: [9]

http://www.cdc.gov/growthcharts/index.htm

Step Therapy Criteria:

Table 2:
First-Line medications which must be tried and failed for an indication before a second-line medication will be approved*

	GHD Children	GHD Transition Adolescent	GHD Adult	Growth Failure due to Chronic Renal Insufficiency	Growth failure in Children Born SGA	Prader-Willi Syndrome	Turner's Syndrome	Noonan Syndrome
First-Line Medication(s)	Genotropin, Norditropin, Nutropin	Genotropin, Norditropin, Nutropin	Genotropin, Norditropin, Nutropin	Nutropin	Genotropin, Norditropin	Genotropin	Genotropin, Norditropin, Nutropin	Norditropin
Second-Line Medication(s)	Humatrope, Omnitrope, Saizen, Zomacton, Zorbtive	Humatrope, Omnitrope, Saizen, Zomacton, Zorbtive	Humatrope, Omnitrope, Saizen, Zomacton, Zorbtive	Genotropin, Humatrope, Norditropin, Omnitrope, Saizen, Zomacton, Zorbtive	Humatrope, Nutropin, Omnitrope, Saizen, Zomacton, Zorbtive	Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Zomacton, Zorbtive	Humatrope, Omnitrope, Saizen, Zomacton, Zorbtive	Genotropin, Humatrope, Nutropin, Omnitrope, Saizen, Zomacton, Zorbtive

* If the requested medication is listed in the "Second-Line Medication(s)" row for the patient's diagnosis, the patient must have tried and failed at least one of the "First-Line Medications" for the diagnosis, before a Second-Line medication may be approved. If the requested medication is one of the "First-Line Medications" for the patient's diagnosis, clinical criteria will apply, but no step therapy will be required.

Clinical Criteria Specific for Diagnosis:

Indication	Approval Criteria	Denial Criteria	Reauthorization Approval Criteria	Reauthorization Denial Criteria
Short stature associated with SHOX deficiency [10, 11, 12, 13]	Diagnosis confirmed by molecular or genetic testing	Diagnosis has not been confirmed by molecular or genetic testing	Pediatric patient who has not reached final adult height or completed linear growth	Patient has reached final adult height or has completed linear growth.
Short stature associated with Noonan Syndrome [13, 14, 15, 16]	Diagnosis confirmed by molecular or genetic testing	○ Diagnosis has not been confirmed by molecular or genetic testing ○ Step Therapy Criteria in Table 1 is not met	Pediatric patient who has not reached final adult height or completed linear growth	Patient who has reached final adult height or completed linear growth
Short stature associated with Turner's Syndrome [10, 13, 17, 18]	Diagnosis confirmed by genetic testing	○ Diagnosis has not been confirmed by genetic testing ○ Step Therapy Criteria in Table 1 is not met	Pediatric patient who has not reached final adult height or completed linear growth	Patient has reached final adult height or has completed linear growth
Short stature associated with Prader-Willi Syndrome [13, 19, 20]	○ Diagnosis confirmed by genetic testing ○ Patient has a BMI less than 35 kg/m^2. ○ Patient does not have severe respiratory impairment or untreated severe obstructive sleep apnea	○ Diagnosis has not been confirmed by genetic testing ○ The patient has a BMI ≥35 kg/m^2. ○ The patient has severe respiratory impairment or untreated severe obstructive sleep apnea. ○ Step Therapy Criteria in Table 1 is not met	○ Patient has a BMI <35 kg/m^2. ○ Patient does not have severe respiratory impairment or untreated severe obstructive sleep apnea ○ Patient has not yet reached final adult height or completed linear growth	○ Patient has reached final adult height or has completed linear growth ○ Patient has a BMI ≥35 kg/m^2. ○ Patient has severe respiratory impairment or untreated severe obstructive sleep apnea

Indication	Approval Criteria	Denial Criteria	Reauthorization Approval Criteria	Reauthorization Denial Criteria
Pediatric growth failure due to chronic kidney disease [13, 20, 21, 22, 23]	○ Patient has a diagnosis of kidney failure with a GFR ≤25 mL/min/1.73 m^2 who is awaiting a kidney transplant. ○ Patient has optimal dietary nutrition (caloric intake). ○ Patient has growth failure as determined by height ≥2 standard deviations below the mean for age and gender ○ Patient has growth velocity <10th percentile of normal for age and gender over the past year	○ Patient does not have a diagnosis of kidney failure with a GFR ≤25 mL/min/1.73 m^2 who is awaiting a kidney transplant. ○ Patient does not have optimal dietary nutrition (caloric intake). ○ Patient does not have growth failure as determined by height ≥2 standard deviations below the mean for age and gender ○ Patient does not have a growth velocity <10th percentile of normal for age and gender over the past year. ○ Patient has attained mid-parental target height. OR ▪ The patient's height is within the 3rd percentile of normal adult height (65 inches for boys and 60 inches for girls). ○ Patient's epiphyses are closed. ○ Step Therapy Criteria in Table 1 is not met	○ Patient has not received a kidney transplant. ○ Patient has previously received ≤3 years of growth hormone treatment. ○ Patient has not attained mid-parental target height. OR ▪ The patient's height is not within the 3rd percentile of normal adult height (65 inches for boys and 60 inches for girls). ○ Patient's epiphyses have not closed.	○ Patient has received a kidney transplant. ○ Patient has previously received >3 years of growth hormone treatment. ○ Patient has attained mid-parental target height. OR ▪ The patient's height is within the 3rd percentile of normal adult height (65 inches for boys and 60 inches for girls). ○ Patient's epiphyses are closed. ○ Patient has reached final adult height or has completed linear growth

Indication	Approval Criteria	Denial Criteria	Reauthorization Approval Criteria	Reauthorization Denial Criteria
Growth failure in children born small for gestational age (includes Intrauterine growth restriction or Russell-Silver syndrome) [24]	○ Patient was born small for gestational age, defined as birth weight or length ≥2 standard deviations (SD) below the mean for gestational age ○ Patient's growth has not caught up before 4 years of age, defined as height <2 SD below the mean for age and gender ○ Other causes for short stature have been ruled out	○ Patient was not born small for gestational age, defined as birth weight or length ≥2 standard deviations (SD) below the mean for gestational age ○ Patient's growth has caught up before 4 years of age, defined as height <2 SD below the mean for age and gender ○ Other causes for short stature have not been ruled out ○ Step Therapy Criteria in Table 1 is not met	○ Patient was born small for gestational age, defined as birth weight or length ≥2 standard deviations (SD) below the mean for gestational age ○ Patient's height has not caught up to being <2 SD below the mean for age and gender ○ Pediatric patient who has not reached final adult height or completed linear growth	○ Patient was not born small for gestational age, defined as birth weight or length ≥2 standard deviations (SD) below the mean for gestational age ○ Patient's height has caught up to being < 2 SD below the mean for age and gender ○ Patient has reached final adult height or has completed linear growth

Indication	Approval Criteria	Denial Criteria	Reauthorization Approval Criteria	Reauthorization Denial Criteria
Diagnosis of growth hormone deficiency in children [13, 20, 25, 26, 27]	○ Patient's epiphyses are open. ○ Patient has been evaluated, and ruled out, for other causes of growth failure (i.e. hypothyroidism, chronic illness, malignancy, celiac disease, malnutrition) ○ Patient has growth failure AND has additional pituitary hormone deficiencies. OR ▪ Patient has growth failure, AND has had surgery or irradiation in the region of the hypothalamus or pituitary. OR ▪ Patient has a growth velocity of ≥2 standard deviations (SD) below the mean for age and gender for the past year OR a. Patient's height is ≥2 SD below the mean for age and gender, AND a growth velocity >1 SD below the mean for age for the past year AND ▪ Patient has had a documented subnormal response to 2 standard GH stimulation tests (defined by a serum GH concentration of <10ng/mL. Tests include insulin-induced hypoglycemia, arginine, glucagon, clonidine, propranolol, or L-dopa) OR a. Subnormal response to one GH stimulation test AND a documented low IGF-1 based on age & gender normal values	○ Patient's epiphyses are closed. ○ Other causes of growth failure have not been ruled out. ○ Patient has a growth velocity of <2 standard deviations (SD) below the mean for age and gender for the past year OR ▪ Patient's height is either <2 SD below the mean for age and gender, OR the growth velocity is ≤1 SD below the mean for age for the past year ○ Patient has not had a documented subnormal response to 2 standard GH stimulation tests. OR ▪ The patient has either not had a subnormal response to one GH stimulation test AND has not had a documented low IGF-1 based on age and gender normal values OR ○ Patient does not have growth failure AND additional pituitary hormone deficiencies. OR ○ Patient does not have growth failure, AND had surgery or irradiation in the region of the hypothalamus or pituitary. ○ Step Therapy Criteria in Table 1 is not met	○ The patient's epiphyses have not closed ○ Patient's pre-treatment growth rate has doubled, OR ▪ Patient has had an increase in pre-treatment growth rate of ≥3 cm/year for the first year of therapy, OR ▪ Patient's growth rate is ≥2.5 cm/year for treatment beyond the first year of therapy ○ The patient has not yet achieved Mid-Parental Height [Please Note: Mid-Parental Height = (father's height + mother's height) ÷ 2, plus 2.5 inches for males, or minus 2.5 inches for females], OR ▪ The patient's height is within the 3rd percentile of normal adult height (65 inches for boys and 60 inches for girls).	○ Bone age = 16 years for males or = 14 years for females ○ The patient's epiphyses have closed ○ Patient's growth rate is <2.5 cm/year for the past year. ○ Whichever occurs sooner: ▪ Either the patient has reached Mid-Parental Height. [Please Note: Mid-Parental Height = (father's height + mother's height) ÷ 2, plus 2.5 inches for males, or minus 2.5 inches for females], OR ▪ The patient's height is within the 3rd percentile of normal adult height (65 inches for boys and 60 inches for girls).

Indication	Approval Criteria	Denial Criteria	Reauthorization Approval Criteria	Reauthorization Denial Criteria
Diagnosis of growth hormone deficiency in a transition patient (an adolescent or young adult patient with childhood-onset GH deficiency, who has completed linear growth, and his/her growth rate is < 2cm/ year): [13, 28]	○ GH treatment has been stopped for at least one month after final height is achieved AND ○ The diagnosis of GHD has been reconfirmed by one of the following, ▪ Patient has ≥3 pituitary hormone deficiencies AND an IGF-1 level <2.5 percentile off GH therapy, OR ▪ Patient has ≤2 pituitary hormone deficiencies AND an IGF-1 level <50th percentile for age and gender, AND a suboptimal response to a growth hormone stimulation test. OR ▪ The patient had childhood-onset growth hormone deficiency AND multiple pituitary hormone deficiencies AND a low IGF-1 level AND has a suboptimal response following at least one growth hormone stimulation test.	○ GH treatment has not been stopped for at least one month after final height is achieved ○ The diagnosis of GHD has not been reconfirmed by one of the following, ▪ Patient has ≥3 pituitary hormone deficiencies AND an IGF-1 level <2.5 percentile off GH therapy. ▪ Patient has ≤2 pituitary hormone deficiencies AND an IGF-1 level <50th percentile for age and gender, AND a suboptimal response to a growth hormone stimulation test. ▪ The patient had childhood-onset growth hormone deficiency AND multiple pituitary hormone deficiencies AND a low IGF-1 level AND had a suboptimal response following at least one growth hormone stimulation test. ▪ Step Therapy Criteria in Table 1 is not met	○ Patient has had a yearly clinical assessment and an evaluation for adverse effects, IGF-1 levels, and other parameters of GH response ○ The patient's clinical assessment indicates that the patient is responding to GH treatment ○ The patient's clinical assessment indicates that the patient continues to need GH treatment.	○ Patient has not had a yearly clinical assessment and an evaluation for adverse effects, IGF-1 levels, and other parameters of GH response ○ The patient's clinical assessment indicates that the patient is not responding to GH treatment. ○ The patient's clinical assessment indicates that the patient no longer needs GH treatment.

Indication	Approval Criteria	Denial Criteria	Reauthorization Approval Criteria	Reauthorization Denial Criteria
Diagnosis of Adult Growth Hormone Deficiency[13, 28]	○ GH treatment has been stopped for at least a month ○ Patient has ≥3 pituitary hormone deficiencies AND ▪ Has an IGF-1 level <2.5th percentile off GH therapy. OR ○ Patient has ≤2 pituitary hormone deficiencies AND ▪ Has an IGF-1 level <50th percentile for age and gender when off GH therapy, AND ▪ Had a suboptimal response to a GH stimulation test. OR ○ Patient history of hypothalamic disease, cranial irradiation, surgery near pituitary gland/ hypothalamus, head trauma or aneurysmal subarachnoid hemorrhage. AND ▪ Patient has multiple pituitary hormone deficiencies, AND ▪ Patient has a serum IGF-1 level below the age and gender appropriate reference range when off GH therapy, AND ▪ Patient had a subnormal response for age to at least one standard GH stimulation test. ○ Documented GHD in childhood AND ▪ Patient had a subnormal response to 2 standard GH stimulation tests after being off GH therapy.	○ GH treatment has not been stopped for at least one month ○ Patient does not have ≥3 pituitary hormone deficiencies AND ▪ An IGF-1 level <2.5 percentile off GH therapy. OR ○ Patient does not have ≤2 pituitary hormone deficiencies AND ▪ IGF-1 level <50th percentile, AND ▪ Suboptimal response to a GH stimulation test. OR ○ Patient without a history of cranial irradiation, hypothalamic disease, surgery near hypothalamus/ pituitary gland, aneurysmal subarachnoid hemorrhage, or head trauma. WITH ▪ Multiple pituitary hormone deficiencies, AND ▪ A serum IGF-1 level below the age and gender appropriate reference range when off GH therapy, AND ▪ A subnormal response to at least one standard GH stimulation test when off GH therapy. ○ Patient has not had a diagnosis of GHD in childhood, AND ▪ A subnormal response to 2 standard GH stimulation tests. ▪ Step Therapy Criteria in Table 1 is not met	○ Patient has had a yearly clinical assessment and an evaluation for adverse effects, IGF-1 levels, and other parameters of GH response. ○ The patient's clinical assessment indicates that the patient is responding to GH treatment ○ The patient's clinical assessment indicates that the patient continues to need GH treatment.	○ Patient has not had a yearly clinical assessment and an evaluation for adverse effects, IGF-1 levels, and other parameters of GH response ○ The patient's clinical assessment indicates that the patient is not responding to GH treatment. ○ The patient's clinical assessment indicates that the patient no longer needs GH treatment.

Denial Criteria for All Requests: [13, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39]

- The patient has one or more of the following contraindications or exclusions to the use of GH therapy:
  - An active malignancy or history of malignancy in the past 12 months
  - Active proliferative or severe non-proliferative diabetic retinopathy
  - An acute critical illness; **OR**,
- Growth hormone is being used for a diagnosis of idiopathic short stature or short bowel syndrome; **OR**,
- Treatment of any diagnosis other than: GH deficiency, Prader-Willi syndrome, Noonan syndrome, SHOX deficiency, Turner's syndrome, growth failure in children born SGA (Including intrauterine growth restriction or Russell-Silver syndrome), or growth failure due to CKD.
  - Some examples of non-approvable diagnoses include: Cystic Fibrosis, Constitutional delay of growth and development, or central precocious puberty; **OR**,
- Being used to increase body mass or strength for professional, recreational, or social reasons (for example: athletes, bodybuilders) ; **OR**,
- Being used to reverse the effects of aging (anti-aging) ; **OR**,
- Being used to counteract an acute or chronic catabolic illness (excluding HIV/AIDs) which is causing protein wasting changes.
  - For example: burns, sepsis, surgery, trauma, cancer, chronic hemodialysis; **OR**,
- Concurrent use with Increlex® (mecasermin).

Length of Authorization:

- Initial coverage may be approved for up to 6 months.
- Subsequent re-authorizations may be approved for 12 months.

Quantity Limit: None

References / Footnotes:

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