



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 4/1/19
LAST REVIEW DATE: 2/21/19
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GROWTH HORMONE THERAPY:

Genotropin® (somatropin) subcutaneous injection
Humatrope® (somatropin) subcutaneous injection
Norditropin® (somatropin) subcutaneous injection
Nutropin AQ® (somatropin) subcutaneous injection
Omnitrope® (somatropin) subcutaneous injection
Saizen® (somatropin) subcutaneous injection
Serostim® (somatropin) subcutaneous injection
Zomacton® (somatropin) subcutaneous injection
Zorbtive® (somatropin) subcutaneous injection

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

GROWTH HORMONE THERAPY (cont.)

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Section A. Applies for all indications and uses:

- **Criteria for initial therapy:** Somatropin injection is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
 1. Prescriber is a physician specializing in or is in consultation with an Endocrinologist, Nephrologist, Infectious Disease, or Trauma/Burn Surgery depending upon indication or use
 2. Meets other initial criteria per indication or use as described below in Sections B-F below
 3. Individual has failure, contraindication or intolerance to the preferred growth hormone therapy medication Nutropin AQ **OR** the preferred growth hormone therapy medication is not indicated for the condition
 4. Somatropin agents or Increlex (mecasermin) will not be used in combination
 5. There are **NO** contraindications (See Definitions section)
 6. Meets other initial criteria as described below in Sections B-G below
 - See section B – for Growth Hormone Deficiency under 18 years of age
 - See section C – for Growth Hormone Deficiency 18 years of age and older
 - See section D – for Burns
 - See section E – for HIV/AIDS Wasting Syndrome
 - See section F – for Short Bowel Syndrome
 - See section G – for Small for Gestational Age
 - See section H – for Idiopathic Short Stature
 - See section I – for Other uses

- **Criteria for continuation of coverage (renewal request):** Somatropin injection is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
 1. Individual continues to be seen by a physician specializing in or is in consultation with an Endocrinologist, Nephrologist, Infectious Disease, or Trauma/Burn Surgery depending upon indication or use
 2. Meets other continuation criteria per indication or use as described in Sections B-F below
 3. Somatropin agents will not be used in combination or in combination with Increlex (mecasermin)

GROWTH HORMONE THERAPY (cont.)

4. Individual has been adherent with the medication
5. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
6. There are no significant interacting drugs
7. Meets other initial criteria as described below in Sections B-I below
 - See section B – for Growth Hormone Deficiency under 18 years of age
 - See section C – for Growth Hormone Deficiency 18 years of age and older
 - See section D – for Burns
 - See section E – for HIV/AIDS Wasting Syndrome
 - See section F – for Short Bowel Syndrome
 - See section G – for Small for Gestational Age
 - See section H – for Idiopathic Short Stature
 - See section I – for Other uses

Section B. Growth Hormone Deficiency for Individuals Under 18 Years of Age:

- **Criteria for initial therapy:** Initial course of treatment of Somatropin injection therapy for **individuals under 18 years of age** may be considered **medically necessary** with documentation of **ALL** of the following:
1. Meets other initial criteria as described in Section A above
 2. A confirmed diagnosis of **ONE** of the following:
 - Individual with **proven growth failure due to growth hormone deficiency (GHD)** as documented by **ALL** of the following:
 - One growth hormone stimulation test with a peak value < 10 ng/mL
 - Bone age is less than the individual's chronological age and the individual's chronological age is prior to gender-appropriate age for bone maturation (14 years for females, 16 years for males)
 - IGF-1 is subnormal result for age as indicated by the table in the Description Section
 - IGFBP-3 is subnormal result for age as indicated by the table in the Description Section
 - Individual with growth failure/short stature due to **chronic renal insufficiency** (defined as a serum creatinine > 1.4 mg/dL (women) or > 1.7 mg/dL (men) or a creatinine clearance of < 75 mL/min/1.73 m²) pending transplantation
 - Individual with growth failure/short stature due to **Noonan's Syndrome**
 - Individual with growth failure/short stature due to **Prader-Willi Syndrome** in the absence of upper airway obstruction or sleep apnea or severe respiratory impairment by sleep study
 - Individuals with growth failure/short stature due to **short stature homeobox-containing gene (SHOX) deficiency**

GROWTH HORMONE THERAPY (cont.)

- Individual with growth failure/short stature due to **Turner's Syndrome** defined as 45, XO genotype
- 3. Documentation that height is at least two standard deviations below the mean for individual's chronologic age and gender
- 4. Individual has recent (within the last 12 months) radiographic evidence of open epiphyses

Initial approval duration:

If approved, may be authorized for a maximum of 12 months

- **Criteria for continuation of coverage (renewal request):** Continuing or repeat courses of treatment of Somatropin injection therapy for individuals **under 18 years of age** are considered **medically necessary** with documentation that the individual has been compliant with treatment **and** documentation of **ANY** of the following:

1. Meets other continuation criteria as described in Section A above
2. Individual's condition responded while on therapy
 - Response is defined as:
 - For proven GHD, Noonan syndrome, Prader-Willi syndrome, SHOX deficiency, or Turner's syndrome:
 - Height has increased at least 2-5 cm/year over the previous year (previous height and date obtained and current height and date obtained must be sent)
 - Has not obtained expected adult height (expected height goal must be sent)
 - For short stature in CRI
 - Individual is pending transplantation (Note: will not be approved if transplantation has occurred)
 - Height has increased at least 2-5 cm/year over the previous year (previous height and date obtained and current height and date obtained must be sent)
 - Has not obtained expected adult height (expected height goal must be sent)
3. Recent (within the last 12 months) radiographic evidence of open epiphyses

Renewal duration:

If approved, may be authorized for a maximum of 12 months per request

Section C. Growth Hormone Deficiency for Individuals 18 Years of Age and Older:

- **Criteria for initial therapy:** Initial course of treatment Somatropin injection therapy for **individuals 18 years of age and older** may be considered **medically necessary** with documentation of **ALL** of the following:
1. Meets other initial criteria as described in Section A above

GROWTH HORMONE THERAPY (cont.)

2. A confirmed diagnosis of **ONE** of the following:
 - Individual with proven **childhood-onset GHD** (acquired or idiopathic or received growth hormone in childhood) **and** whose epiphyses have closed with documentation of **ALL** of the following:
 - Individual has been **retested** to determine if on-going replacement therapy is needed
 - The results of **TWO** abnormal provocative stimulation tests demonstrate growth hormone peak value < 5 ng/mL by RIA **or** peak value < 2.5 ng/mL by IRMA (Note: time of administration of the provocative agent & the number of minutes elapsed between provocative agent administration time and drawing of serum GH level must be sent)
 - Individual with **suspected adult-onset GHD** with documentation of the following:
 - The results of **TWO** abnormal provocative stimulation tests demonstrate growth hormone peak value < 5 ng/mL by RIA **or** peak value < 2.5 ng/mL by IRMA (Note: time of administration of the provocative agent & the number of minutes elapsed between provocative agent administration time and drawing of serum GH level must be sent)
 - Individual with surgery, irradiation or trauma involving the hypothalamus or pituitary gland, or other diseases of the hypothalamus or pituitary gland with documentation of **ALL** of the following:
 - The results of **ONE** abnormal provocative stimulation test demonstrate growth hormone peak value < 5 ng/mL by RIA **or** peak value < 2.5 ng/mL by IRMA (Note: time of administration of the provocative agent & the number of minutes elapsed between provocative agent administration time and drawing of serum GH level must be sent)
 - Individual with **multiple pituitary hormone deficiencies other than growth hormone** (i.e., TSH, ACTH, LH and/or FSH, AVP) **and** serum insulin-like growth factor 1 (IGF-1) less than the lower limit of normal for the assay that was used
 - Individual with **congenital/genetic growth hormone deficiency** such as Noonan syndrome, Prader-Willi Syndrome, short stature homeobox-containing gene (SHOX) deficiency, or Turner's syndrome

Initial approval duration:

If approved, may be authorized for a maximum of 12 months.

- **Criteria for continuation of coverage (renewal request):** Continuing or repeat courses of treatment of Somatropin injection therapy for **individuals 18 years of age and older** are considered **medically necessary** with documentation that the individual has been compliant with treatment **and** documentation of **ANY** of the following:
1. Meets other continuation as described in Section A above
 2. Individual's condition responded while on therapy
 - Individual with proven childhood-onset GHD (acquired or idiopathic or received growth hormone in childhood) or suspected adult-onset GHD
 - Historical clinical records of two abnormal provocative stimulation tests

GROWTH HORMONE THERAPY (cont.)

- Individual with surgery, irradiation or trauma involving the hypothalamus or pituitary gland or other diseases of the pituitary or hypothalamus
 - Historical clinical records of one abnormal provocative stimulation test
 - Clinical records document that without ongoing treatment with growth hormone (GH), signs or symptoms of GH deficiency would reappear, or if a gap in treatment occurred, low GH levels or signs and symptoms of GH deficiency reappeared
3. Individual with multiple pituitary hormone deficiencies other than growth hormone (i.e., TSH, ACTH, LH and/or FSH, AVP) **and** serum insulin-like growth factor 1 (IGF-1) less than the lower limit of normal for the assay that was used
 4. Individual with congenital/genetic growth hormone deficiency such as Noonan syndrome, Prader-Willi Syndrome, short stature homeobox-containing gene (SHOX) deficiency, or Turner's syndrome

Renewal duration:

If approved, may be authorized for a maximum of 12 months per request

Section D. Burns:

- **Criteria for initial therapy:** Somatropin injection therapy is considered **medically necessary** for the treatment of severe burns with documentation of **ALL** the following:
1. Meets other initial criteria per indication or use as described in Section A above
 2. A confirmed diagnosis of **ONE** of the following:
 - Individual with extensive 3rd degree burns showing difficulty with wound healing
 - Children with severe burns that cover at least 40% of total body surface area, to prevent growth delay

Approval duration: For up to 1 year after the burn

Section E. HIV/AIDS Wasting: (Serostim only)

- **Criteria for initial therapy:** Serostim for the treatment of HIV/AIDS wasting syndrome or cachexia is considered **medically necessary** with documentation of **ALL** of the following:
1. Meets other initial criteria as described in Section A above
 2. Individual is 18 years of age or older
 3. There is **ONE** of the following:
 - Unintentional/involuntary weight loss of at least 10% of ideal (standard) body weight for height and weight (see women's/men's weight at different ages charts in Definitions Section) within the last 12 months

GROWTH HORMONE THERAPY (cont.)

- Unintentional/involuntary weight loss to a BMI of < 20 kg/m²
- 4. Weight loss is not explained by another concurrent illness other than HIV/AIDS infection
- 5. There is continued weight loss despite adequate nutrition and other measures
- 6. Individual is currently receiving optimal antiretroviral drug therapy for HIV/AIDS positive disorder to decrease the viral load
- 7. Will not be used as intermittent therapy for maintenance
- 8. Individual has failure, contraindication or intolerance to megestrol or dronabinol

Initial approval duration: 12 weeks

- **Criteria for continuation of coverage (renewal request):** Serostim for the treatment of HIV/AIDS wasting syndrome or cachexia is considered **medically necessary** with documentation of **ALL** of the following:
1. Meets other continuation criteria as described in Section A above
 2. Individual's condition responded while on therapy
 - Response is defined as:
 - Weight loss has improved or weight has stabilized during the initial 12 weeks but target body mass index or weight has not been achieved
 3. Individual is currently receiving optimal antiretroviral drug therapy for HIV/AIDS positive disorder to decrease the viral load
 4. Will not be used as intermittent therapy for maintenance

Renewal duration: Total course: 48 weeks (includes the duration of use under Initial approval)

Section F. Short Bowel Syndrome: (Zorbtive only)

- **Criteria for therapy:** Zorbtive for the treatment of short bowel syndrome is considered **medically necessary** with documentation of **ALL** of the following:
1. Meets other initial criteria as described in Section A above
 2. Individual is 18 years of age or older
 3. Documentation that at least 50% of the small intestine has been removed

GROWTH HORMONE THERAPY (cont.)

- Individual is on concurrent specialized nutritional support (i.e., high-carbohydrate, low-fat diet adjusted for individual patient requirements, such as dietary adjustments, enteral feedings, parenteral nutrition, fluid and micronutrient supplements)
- There is **NO** history of previous use of Zorbtive for 4 weeks for short bowel syndrome

Approval duration: Single 4-week course only

Section G. Small for Gestational Age (SGA):

COVERAGE FOR TREATMENT TO CORRECT A CONGENITAL DEFECT OR BIRTH ABNORMALITY IS DEPENDENT UPON BENEFIT PLAN LANGUAGE AND IS SUBJECT TO THE PROVISIONS OF THE RECONSTRUCTIVE BENEFIT AND THE COSMETIC BENEFIT EXCLUSION. REFER TO MEMBER'S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS AND THE FUNCTIONAL IMPAIRMENT REQUIREMENT.

- **Somatropin injection therapy for the treatment of children born *small for gestational age (SGA)***, including those who have failed to manifest "catch-up" growth by two years of age, is considered ***not medically necessary*** and ***not eligible for coverage*** due to lack of an associated functional impairment.

Section H. Idiopathic Short Stature (ISS):

- **Somatropin injection therapy for treatment of *idiopathic short stature***, without documentation of growth hormone deficiency, is a ***benefit plan exclusion*** and ***not eligible for coverage***.

Section I. Other Uses:

- **Somatropin injection therapy for all other indications not previously listed** is considered ***experimental or investigational*** based upon:
 - Lack of final approval from the Food and Drug Administration, and
 - Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 - Insufficient evidence to support improvement of the net health outcome, and
 - Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 - Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:

- Improvement of neurodevelopmental status (intelligence)
- Prevention of dyslipidemia, insulin resistance and/or metabolic syndrome (diabetes, hypertension, obesity)
- Altered body habitus, e.g., buffalo hump, associated with antiviral therapy in individuals with HIV
- Anabolic therapy to counteract acute or chronic illness (surgery outcomes, trauma, cancer, chronic hemodialysis, chronic infectious disease) that produces catabolic (protein wasting) changes in both adults and children, except as specified for AIDS and short bowel syndrome

GROWTH HORMONE THERAPY (cont.)

- Anabolic therapy to counteract the gradual declines in muscle and bone mass that occur with aging
- Anabolic therapy to enhance body mass and strength for professional, recreational or social reasons
- Constitutional delay
- Cystic fibrosis
- Growth failure as the result of glucocorticoids
- Idiopathic dilated cardiomyopathy
- Intrauterine growth retardation
- Juvenile idiopathic or juvenile chronic arthritis
- Obesity
- Precocious puberty in conjunction with gonadotropin releasing hormone (GnRH) analogs
- Short stature after renal transplantation
- Short stature as the result of Down Syndrome
- Treatment of children with “genetic potential” (i.e., lower than expected height percentiles based on parents’ height)
- Treatment with dosing or frequency outside the FDA-approved dosing and frequency

Description:

Somatropin is a synthetically produced growth hormone (GH). Somatropin is indicated for the treatment of growth hormone deficiency (GHD), short stature associated with Turner syndrome (TS) or Noonan syndrome (NS), short-stature homeobox (SHOX) gene deficiency, growth failure due to Prader-Willi syndrome (PWS), short stature in children born small for gestational age (SGA), growth failure in children with chronic renal insufficiency (CRI) or chronic kidney disease (CKD) up to the time of transplant, idiopathic short stature (ISS), to promote wound healing in burns, short bowel syndrome (SBS) in patients receiving specialized nutritional support, and HIV-associated wasting. Somatropin is also indicated for replacement of endogenous growth hormone in adults with confirmed GHD. Short stature, such as in idiopathic short stature (ISS) and in small for gestational age (SGA), in the absence of defined pathology is not a sickness or injury; growth hormone is not a covered health service for these indications.

Growth Hormone Deficiency (GHD) is defined as the inadequate secretion of endogenous growth hormone. GHD may be idiopathic or organic and can occur in childhood or adulthood. Pathophysiology differs between the two onsets. GHD is diagnosed through a combination of clinical and biochemical examination, testing and analysis.

Children with GHD generally present with short stature and growth velocity that is two (2) standard deviations below the mean for chronologic age, sex and pubertal stage. Often the etiology is isolated idiopathic GHD.

GHD in adults often results from conditions affecting the hypothalamus or pituitary gland including surgery and radiation therapy. Adults frequently report symptoms such as unintentional weight gain or difficulty losing weight, low energy, reduced physical performance, decreased libido, impaired psychological well-being and a feeling that things are not right. Physical findings may include increased fat mass, decreased lean body and muscle mass, decreased bone density as well as reduced muscle strength and exercise capacity. There is however no single symptom or sign that is pathognomonic for GHD in adults. In addition, some adults with GHD may be entirely asymptomatic.

GROWTH HORMONE THERAPY (cont.)

Growth Hormone (GH) provocative stimulation test is one of the procedures that may be performed to diagnose growth hormone deficiency (GHD). A provocative agent is used to stimulate the pituitary gland to secrete GH. The intent is to determine the maximum peak GH response from the provocative agent. The peak is the value used to determine whether the response is considered normal or abnormal for the purpose of supporting the diagnosis of GHD. Serum levels may be measured by radioimmunoassay (RIA) or immunoradiometric assay (IRMA).

GH secretion is pulsatile. There are approximately 10 pulses of GH secretion per day, lasting approximately 90 minutes and separated by roughly 128 minutes. Nearly 50% of samples collected during the day in normal subjects have undetectable serum GH concentrations. In addition, GH is undetectable in over 95% of samples in obese or older subjects.

Baseline testing is performed prior to administration of the provocative agent and frequent blood sampling is done thereafter. Sampling occurs approximately 30, 60, 90, 120 and 180 minutes after provocative agent administration. Sampling defines the “curve” of the response (going from a lower GH value prior to provocation to the highest, or peak, GH value after provocation and then a drop from peak) and must provide sufficient information to determine a peak value.

Definitions:

Adult: Age 18 years and older

Somatropin products:

Genotropin
Humatrope
Norditropin
Nutropin AQ – preferred product
Omnitrope
Saizen
Serostim
Zomacton
Zorbtive

Contraindications to use of somatropin include:

- Active malignancy
- Active proliferative or severe non-proliferative diabetic retinopathy
- Acute critical illness in response to open heart surgery, abdominal surgery, multiple accidental trauma, or acute respiratory failure
- Growth promotion in pediatric individuals with closed epiphysis
- Pediatric individuals with Prader-Willi syndrome who are severely obese or have history of upper airway obstruction or sleep apnea or have severe respiratory impairment by sleep study
- Known hypersensitivity to the drug or any diluent (benzyl alcohol, m-cresol) or any other ingredient of the formulation

GROWTH HORMONE THERAPY (cont.)

Growth Hormone (GH) Provocative Stimulation Tests:

- Arginine HCL Test
- Arginine/L-Dopa Test
- Clonidine Test
- Glucagon Stimulation Test
- Growth Hormone Releasing Hormone Test (GHRH)
- Insulin Tolerance Test (ITT) or Insulin Induced Hypoglycemic Test
- L-Dopa Test
- Propranolol/Glucagons Test
- Physiological: sleep-induced or exercise-induced stimulation
- Macimorelin: a ghrelin agonist

Insulin-Like Growth Factor 1 (IGF-1):

A hormone created mainly by the liver that mediates most of the effects of growth hormone. IGF-1 blood tests may be used in the diagnosis of growth hormone deficiency.

AGE	SUBNORMAL RESULT
7 years ¹	Less than 52 ng/mL
8 through 10 years	Less than 75 ng/mL
11 through 12 years	Less than 127 ng/mL
13 through 17 years	Less than 212 ng/mL

¹ Limited safety and efficacy data are available below the age of 7.

Insulin-Like Growth Factor Binding Protein (IGFBP-3):

The transport protein for IGF-1 and IGF-2 in the circulation. It modulates IGF activity and inhibits cell growth. Its levels increase in the presence of IGF-I, insulin and other growth-stimulating factors such as growth hormone. IGFBP-3 blood tests may be used in the diagnosis of growth hormone deficiency.

AGE	SUBNORMAL RESULT	AGE	SUBNORMAL RESULT
7 years ¹	Less than 1.4 mg/L	13 years	Less than 3.1 mg/L
8 years	Less than 1.6 mg/L	14 years	Less than 3.1 mg/L
9 years	Less than 1.8 mg/L	15 years	Less than 3.5 mg/L
10 years	Less than 2.1 mg/L	16 years	Less than 3.4 mg/L
11 years	Less than 2.4 mg/L	17 years	Less than 3.2 mg/L
12 years	Less than 2.7 mg/L		

¹ Limited safety and efficacy data are available below the age of 7.

Functional Impairment:

A state in which the normal or proper action (function) of any body part or organ is damaged or deficient as a result of growth hormone deficiency.

GROWTH HORMONE THERAPY (cont.)

Burn evaluation:

Extent of total body surface area expressed as a percent

- Rule of 9s for adult:
 - Head 9%
 - Each arm 9%
 - Anterior chest and abdomen 18%
 - Posterior chest and back 18%
 - Each leg 18%
 - Perineum 1%
- Rule of 9s for child:
 - Head 18%
 - Each leg 13.5%
 - Then the rest as above

Depth of burn, estimates the depth of burn affecting the outer epidermis and dermis:

- First degree: superficial, only involves the epidermis
- Second degree: partial thickness, extends through the epidermis and into the dermis
- Third degree: full thickness, extends through the epidermis, into the dermis and into the subcutaneous fat
- Fourth degree: damage the underlying bones, muscles, and tendons

Short Bowel Syndrome:

A malabsorption syndrome resulting from surgical removal of at least 50% of the small intestine. According to the American Gastroenterological Association, SBS is a disorder that is defined clinically as malabsorption, diarrhea, fluid and electrolyte disturbances, and malnutrition. In SBS there is functional or anatomical loss of extensive segments of the small intestines, with resultant compromised absorptive capacity.

Idiopathic Short Stature (ISS):

ISS (also known as non-growth hormone-deficient short stature) is extreme short stature that does not have a diagnostic explanation after a growth evaluation documenting normal physical function and normal lab tests. ISS includes short stature without documentation of growth hormone deficiency and children are identified as being abnormally short. ISS may also be referred to as short stature of undefined cause.

Small for gestational age (SGA):

A term used to describe a baby who is smaller than the usual amount for the number of weeks of pregnancy. SGA is most commonly defined as a weight below the 10th percentile for the gestational age.

Abnormally Short:

Boys: Height predicted to be shorter than 5 feet 3 inches

Girls: Height predicted to be shorter than 4 feet 11 inches

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GROWTH HORMONE THERAPY (cont.)

Body weight for height charts for woman and men:

WEIGHT FOR WOMEN AT DIFFERENT AGES

Height	Age 18 to 29			Age 30 to 44			Age 45 to 65		
	25%		40%	25%		40%	25%		40%
	UW	SW	OW	UW	SW	OW	UW	SW	OW
4'11"	85	113	158	89	119	167	95	126	176
5'0"	86	114	160	92	122	171	97	129	181
5'1"	87	116	162	93	124	174	99	132	185
5'2"	89	118	165	95	127	178	101	135	189
5'3"	92	122	171	98	131	183	104	139	195
5'4"	94	125	175	101	134	188	107	143	200
5'5"	96	128	179	104	139	195	111	148	207
5'6"	99	132	185	107	143	200	114	152	213
5'7"	101	135	189	110	147	206	116	155	217
5'8"	105	140	196	113	151	211	119	159	223
5'9"	108	144	202	116	155	217	123	164	230
5'10"	110	147	206	119	159	223	126	168	235
5'11"	112	149	209	122	163	228	129	172	241
6'0"	113	151	211	125	167	234	132	176	246
6'1"	115	153	214	127	169	237	135	180	252
6'2"	116	155	217	128	171	239	138	184	258

Legend: UW: underweight SW: standard weight OW: over weight



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GROWTH HORMONE THERAPY (cont.)

WEIGHT FOR MEN AT DIFFERENT AGES

Height	Age 18 to 29			Age 30 to 44			Age 45 to 65		
	25%		40%	25%		40%	25%		40%
	UW	SW	OW	UW	SW	OW	UW	SW	OW
5'0"	94	125	175	98	131	183	101	134	188
5'1"	95	126	176	99	132	185	102	136	190
5'2"	96	128	179	100	133	186	104	138	193
5'3"	98	131	183	102	136	190	106	141	197
5'4"	101	135	189	105	140	196	109	145	203
5'5"	104	138	193	107	143	200	112	149	209
5'6"	107	142	199	110	147	206	115	153	214
5'7"	110	147	206	114	152	213	119	158	221
5'8"	113	151	211	118	157	220	122	163	228
5'9"	116	155	217	122	162	227	126	168	235
5'10"	119	159	223	125	167	234	130	173	242
5'11"	123	164	230	130	173	242	134	178	249
6'0"	128	170	238	134	179	251	137	183	256
6'1"	133	177	248	139	185	259	142	189	264
6'2"	138	184	258	145	193	270	146	194	272
6'3"	143	190	266	149	198	277	150	200	280
6'4"	147	196	274	152	203	284	155	206	288
6'5"	151	201	281	155	207	290	158	211	295
6'6"	155	206	288	158	211	295	162	216	302
6'7"	157	209	293	161	215	301	166	221	309
6'8"	161	214	300	164	219	307	170	226	316

Legend: UW: underweight SW: standard weight OW: over weight

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Summary of FDA-approved Indications:

Somatropin: Summary of FDA Indications									
	Genotropin	Humatrope	Norditropin	Nutropin AQ	Omnitrope	Saizen	Serostim	Zomacton †	Zorbtive
Condition									
Adult GHD ^a	✓	✓	✓	✓	✓	✓		✓	
Pediatric GHD ^b	✓	✓	✓	✓	✓	✓		✓	
Growth failure with CKD ^c				✓					
Idiopathic short stature (ISS) ^d	✓	✓	✓	✓	✓			✓	
Noonan syndrome (NS)			✓						
Prader-Willi syndrome (PWS)	✓		✓		✓				
Short bowel syndrome (SBS)									✓
SHOX deficiency ^e		✓						✓	
Turner syndrome (TS)	✓	✓	✓	✓	✓			✓	
Small for gestational age (SGA)	✓ ^g	✓ ^h	✓ ^h		✓ ^g			✓	
Wasting or cachexia in adults with HIV ^f							✓		

^a Adult Growth hormone deficiency (**GHD**) may be either: (1) **adult-onset** (patients who have GHD, either alone or associated with multiple hormone deficiencies [hypopituitarism], as a result of pituitary disease, hypothalamic disease, surgery, radiation, or trauma) or (2) **childhood-onset** (patients who were GHD during childhood as a result of congenital, genetic, acquired, or idiopathic causes). Patients who were treated with somatropin for GHD in childhood and whose epiphyses are closed should be reevaluated before continuation of somatropin therapy at the reduced dose level recommended for GHD adults. According to current standards, confirmation of the diagnosis of adult growth hormone deficiency in both of the above groups involves an appropriate growth hormone provocative test with two exceptions: (1) patients with multiple other pituitary hormone deficiencies due to organic disease; and (2) patients with congenital/genetic growth hormone deficiency

^b Caused by an inadequate secretion of endogenous growth hormone

^c CKD = chronic kidney disease. Use up until the time of renal transplantation and in conjunction with optimal management of CKD.

^d Also called non-growth hormone-deficient short stature (defined by height standard deviation score [SDS] less than or equal to -2.25) and associated with growth rates unlikely to permit attainment of adult height in the normal range in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means.

^e SHOX = short stature homeobox-containing gene

^f Concomitant antiretroviral therapy is necessary

^g For children who fail to manifest catch-up growth by 2 years of age

^h For children with no catch-up growth by 2 to 4 years of age

[†] Brand Tev-Tropin was renamed to Zomacton

Resources:

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UpToDate: Diagnosis of growth hormone deficiency in children. Current through Nov 2018. https://www.uptodate-com.mwu.idm.oclc.org/contents/diagnosis-of-growth-hormone-deficiency-in-children?search=growth%20hormone&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4

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PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 4/1/19
LAST REVIEW DATE: 2/21/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

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UpToDate: Growth hormone metabolism in chronic kidney disease. Current through Nov 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/growth-hormone-metabolism-in-chronic-kidney-disease?search=growth%20hormone&source=search_result&selectedTitle=8~150&usage_type=default&display_rank=8



An Independent Licensee of the Blue Cross and Blue Shield Association

Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com. Call 866-325-1794 to check the status of a request. All requested data must be provided. Incomplete forms or forms without the chart notes will be returned. Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information		
Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information			
Medication Name:	Strength:	Dosage Form:	
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

Check if requesting **brand** only Check if requesting **generic**

Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review	
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____	<input type="checkbox"/> Exigent (requires prescriber to include a written statement)

Clinical Information	
1. What is the diagnosis? Please specify below. ICD-10 Code: _____ Diagnosis Description: _____	
2. <input type="checkbox"/> Yes <input type="checkbox"/> No	Was this medication started on a recent hospital discharge or emergency room visit?
3. <input type="checkbox"/> Yes <input type="checkbox"/> No	There is absence of ALL contraindications.

4. What medication(s) has the individual tried and failed for this diagnosis? Please specify below.
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. Are there any supporting labs or test results? Please specify below.

Date	Test	Value

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature:	Date:
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Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.