



MEDICAL COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 09/10/09  
LAST REVIEW DATE: 12/18/13  
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## GROWTH HORMONE THERAPY

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

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.

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

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

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### Description:

Somatotropin is a synthetically produced growth hormone (GH). It has been used in the treatment of growth hormone deficiency, Noonan, Turner and Prader-Willi Syndromes, to promote wound healing in burns, for AIDS wasting and for short bowel syndrome. It has also been investigated as a treatment for other conditions.

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**GROWTH HORMONE THERAPY (cont.)**

**Description:** (cont.)

The following table lists a variety of FDA-approved GH products and indications:

	Genotropin®	Humatrope®	Norditropin®	Nutropin® Nutropin AQ®	Saizen®	Serostim®	Tev-Tropin®	Zorbtive™	Omnitrope™
Growth failure in pediatric individuals (under 18 years of age) with inadequate endogenous growth hormone	Yes	Yes	Yes	Yes	Yes		Yes		Yes
Growth failure due to Prader-Willi Syndrome	Yes								Yes
Replacement therapy in adults (individuals 18 years of age and older) with growth hormone deficiency	Yes	Yes	Yes	Yes	Yes				Yes
Growth failure associated with chronic renal insufficiency				Yes					
HIV wasting or cachexia (AIDS wasting)						Yes			
Children born small for gestational age who fail to show catch-up growth by age 2	Yes	Yes	Yes						Yes
Idiopathic Short stature	Yes	Yes		Yes					
Short stature due to Turner's Syndrome (45, XO)	Yes	Yes	Yes	Yes					Yes
Treatment of short bowel syndrome								Yes	
Short stature in pediatric individuals with short stature homeobox-containing gene (SHOX) deficiency		Yes							
Short stature in pediatric individuals with Noonan Syndrome			Yes						

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## **GROWTH HORMONE THERAPY (cont.)**

### **Description: (cont.)**

#### Growth Hormone Deficiency (GHD):

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:

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.

#### 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 (GH) Provocative Stimulation Test:

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. This 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).

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.

Examples of this test are:

- Arginine HCL Test
- Arginine/L-Dopa Test
- Clonidine Test
- Glucagon Stimulation Test
- Growth Hormone Releasing Hormone Test (Geref)
- Insulin Tolerance Test (ITT) or Insulin Induced Hypoglycemic Test
- L-Dopa Test
- Propranolol/Glucagons Test
- Physiological: Sleep-induced or exercise-induced stimulation



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## GROWTH HORMONE THERAPY (cont.)

### Description: (cont.)

#### 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.

#### 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. Idiopathic short stature includes short stature without documentation of growth hormone deficiency and children identified as abnormally short. ISS may also be referred to as short stature of undefined cause.

#### 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.

#### 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-1, insulin and other growth-stimulating factors such as growth hormone. IGFBP-3 blood tests may be used in the diagnosis of growth hormone deficiency.

#### Abnormally Short:

Boys: Height predicted to be shorter than 5 feet 3 inches  
Girls: Height predicted to be shorter than 4 feet 11 inches

#### Short Bowel Syndrome:

Malabsorption syndrome resulting from surgical removal of at least 50% of the small intestine.

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## GROWTH HORMONE THERAPY (cont.)

### Criteria:

#### Growth Hormone Deficiency for Individuals Under 18 Years of Age:

##### Initial Course of Treatment:

Initial requests for growth hormone therapy for treatment of growth hormone deficiency will be reviewed by the clinical pharmacist and/or medical director(s) and/or clinical advisor(s) and, if approved, may be authorized for a maximum of 12 months.

- An initial course of growth hormone therapy may be considered **medically necessary** with documentation of **ANY** of the following:
  1. Individual with growth failure due to growth hormone deficiency as documented by **ALL** of the following:
    - Results of one (1) growth hormone stimulation test demonstrating a peak value of less than 10ng/ml (unless otherwise contraindicated)
    - Bone age is less than chronological age and individual's chronological age is prior to gender-appropriate mature bone age (14 years for females, 16 years for males)
    - Height at least two (2) standard deviations below the mean for chronologic age
    - IGF-1 with subnormal result for age as indicated by the following table:

AGE	SUBNORMAL RESULT
7 years*	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

- IGFBP-3 with subnormal result for age as indicated by the following table:

AGE	SUBNORMAL RESULT	AGE	SUBNORMAL RESULT
7 years*	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		

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

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## GROWTH HORMONE THERAPY (cont.)

Criteria: (cont.)

Growth Hormone Deficiency for Individuals Under 18 Years of Age: (cont.)

Initial Course of Treatment: (cont.)

- An initial course of growth hormone therapy may be considered **medically necessary** with documentation of **ANY** of the following: (cont.)
  1. Individual with growth failure due to growth hormone deficiency as documented by **ALL** of the following: (cont.)
    - Diagnostic tests have ruled out treatable causes. These tests include:
      - Cranial MRI and T<sub>4</sub>
      - FSH
      - Cortisol
  2. Individual with height less than the 3<sup>rd</sup> percentile for chronological age secondary to chronic renal insufficiency up to the time of renal transplantation
  3. Individual 3 through 17 years of age with growth failure due to Noonan's Syndrome with documented short stature
  4. Individual with Turner's Syndrome
  5. Individual with growth failure due to Prader-Willi Syndrome with documented absence of upper airway obstruction or sleep apnea by sleep study
  6. Individuals with short stature due to short stature homeobox-containing gene (SHOX) deficiency.
- **If the above criteria are not met**, the initial course of treatment of growth hormone therapy for growth hormone deficiency is considered **experimental or investigational** due to:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

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## GROWTH HORMONE THERAPY (cont.)

Criteria: (cont.)

Growth Hormone Deficiency for Individuals Under 18 Years of Age: (cont.)

Continuing and Repeat Courses of Treatment:

Requests for continuing or repeat courses of growth hormone therapy will be reviewed annually to determine if growth hormone therapy continues to be medically necessary and, if approved, may be authorized for a maximum of 12 months per request. Requests not meeting criteria below will be reviewed by the clinical pharmacist and/or medical director(s) and/or clinical advisor(s).

- Continuing or repeat courses of growth hormone therapy are considered **medically necessary** with documentation that the individual has been compliant with treatment **and** documentation of **ANY** of the following:
  1. Individual with growth failure due to growth hormone deficiency as documented by **ALL** of the following:
    - Historical clinical records include results of one (1) growth hormone stimulation test demonstrating a peak value of less than 10 ng/ml **with** appropriate timing of provocative agent administration (unless otherwise contraindicated) (see Description section)
    - Growth velocity is 5 cm or greater over the year (i.e. past 12 months) of treatment **and** individual's growth plates have not fused
  2. Individual with height less than the 3<sup>rd</sup> percentile for chronological age secondary to chronic renal insufficiency up to the time of renal transplantation
  3. Individual 3 through 17 years of age with growth failure due to Noonan's Syndrome with documented short stature
  4. Individual with Turner's Syndrome
  5. Individual with growth failure due to Prader-Willi Syndrome with documented absence of upper airway obstruction or sleep apnea by sleep study
  6. Individuals with short stature due to short stature homeobox-containing gene (SHOX) deficiency.
- **If the above criteria are not met**, continuing or repeat courses of treatment of growth hormone therapy for growth hormone deficiency are considered **experimental or investigational** due to:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

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## GROWTH HORMONE THERAPY (cont.)

Criteria: (cont.)

### Growth Hormone Deficiency for Individuals 18 Years of Age and Older:

#### Initial Course of Treatment:

Initial requests for growth hormone therapy for treatment of growth hormone deficiency will be reviewed by the clinical pharmacist and/or medical director(s) and/or clinical advisor(s) and, if approved, may be authorized for a maximum of 12 months.

- An initial course of growth hormone therapy may be considered **medically necessary** with documentation of **ANY** of the following:
  1. Growth hormone deficiency (GHD) with documentation of **ALL** of the following:
    - Individual with proven childhood-onset GHD retested to determine if on-going replacement therapy is needed **or** individual with suspected adult-onset GHD
    - Results of two (2) provocative stimulation tests demonstrating peak value less than 5ng/ml when measured by RIA, **or** peak value less than 2.5ng/ml when measured by IRMA
    - Time of administration of the provocative agent
    - Number of minutes elapsed between provocative agent administration time and drawing of serum GH level
  2. Individual with surgery, irradiation or trauma involving the hypothalamus or pituitary gland or other diseases of the pituitary or hypothalamus with documentation of **ALL** of the following:
    - Results of one (1) provocative stimulation test demonstrating peak value less than 5ng/ml when measured by RIA, **or** peak value less than 2.5ng/ml when measured by IRMA
    - Time of administration of the provocative agent
    - Number of minutes elapsed between provocative agent administration time and drawing of serum GH level
    - Clinical records document that without treatment, low GH levels result **and/or** signs and symptoms of growth hormone deficiency reappear
  3. Individual with multiple pituitary hormone deficiencies other than growth hormone (i.e., TSH, ACTH, LH and/or FSH, AVP) **or** serum insulin-like growth factor 1 (IGF-1) less than 84 ng/mL
  4. Individual with Turner's Syndrome

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## GROWTH HORMONE THERAPY (cont.)

Criteria: (cont.)

Growth Hormone Deficiency for Individuals 18 Years of Age and Older: (cont.)

Initial Course of Treatment: (cont.)

- **If the above criteria are not met**, the initial course of growth hormone therapy for the treatment of growth hormone deficiency is considered **experimental or investigational** due to:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

Continuing and Repeat Courses of Treatment:

**Requests for continuing or repeat courses of growth hormone therapy will be reviewed annually to determine if growth hormone therapy continues to be medically necessary and, if approved, may be authorized for a maximum of 12 months per request. Requests not meeting criteria below will be reviewed by the clinical pharmacist and/or medical director(s) and/or clinical advisor(s).**

- Continuing or repeat courses of growth hormone therapy are considered **medically necessary** with documentation that the individual has been compliant with treatment **and** documentation of **ANY** of the following:
  1. Individual with historical diagnosis of proven growth hormone deficiency (GHD) with documentation of **ALL** of the following:
    - **ONE** of the following historical clinical records:
      - Results of two (2) provocative stimulation tests demonstrating peak value less than 5ng/ml when measured by RIA **with** appropriate timing of provocative agent administration
      - Results of two (2) provocative stimulation tests demonstrating peak value less than 2.5ng/ml when measured by IRMA **with** appropriate timing of provocative agent administration
    - 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 had occurred, low GH levels or signs and symptoms of GH deficiency have reappeared

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## GROWTH HORMONE THERAPY (cont.)

Criteria: (cont.)

Growth Hormone Deficiency for Individuals 18 Years of Age and Older: (cont.)

Continuing and Repeat Courses of Treatment: (cont.)

2. Individual with surgery, irradiation or trauma involving the hypothalamus or pituitary gland or other diseases of the pituitary or hypothalamus with documentation of **ALL** of the following:
  - **ONE** of the following historical clinical records:
    - Results of one (1) provocative stimulation test demonstrating peak value less than 5ng/ml when measured by RIA **with** appropriate timing of provocative agent administration (see Description section)
    - Results of one (1) provocative stimulation test demonstrating peak value less than 2.5ng/ml when measured by IRMA **with** appropriate timing of provocative agent administration (see Description section)
  - 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 had occurred, low GH levels or signs and symptoms of GH deficiency have reappeared
3. Individual with multiple pituitary hormone deficiencies other than growth hormone (i.e., TSH, ACTH, LH and/or FSH, AVP) **or** serum insulin-like growth factor 1 (IGF-1) less than 84 ng/mL
4. Individual with Turner's Syndrome



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## GROWTH HORMONE THERAPY (cont.)

Criteria: (cont.)

Growth Hormone Deficiency for Individuals 18 Years of Age and Older: (cont.)

Continuing and Repeat Courses of Treatment: (cont.)

- **If the above criteria are not met**, continuing or repeat courses of treatment of growth hormone therapy for treatment of growth hormone deficiency are considered **experimental or investigational** due to:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

Growth Failure:

**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.**

- Growth hormone 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.
- Growth hormone therapy for treatment of growth failure for all other indications not previously listed is considered **experimental or investigational** based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. 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)

Idiopathic Short Stature:

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

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## **GROWTH HORMONE THERAPY (cont.)**

**Criteria:** (cont.)

### **Wound Healing for Burns:**

- Growth hormone therapy is considered **medically necessary** for the promotion of wound healing in extensive 3<sup>rd</sup> degree burns.
- Growth hormone therapy is considered **medically necessary** for the prevention of growth delay in children with severe burns.

### **Other Indications:**

- Growth hormone therapy for all other indications not previously listed is considered **experimental or investigational** based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome.

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

- 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
- 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)

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## GROWTH HORMONE THERAPY (cont.)

**Criteria:** (cont.)

**Serostim:**

**AIDS Wasting:**

- Serostim for the treatment of adults with AIDS wasting is considered **medically necessary** for an initial 2-week trial course with documentation of **ALL** of the following:
  1. Weight loss is greater than or equal to 10% of ideal ( standard ) body weight for height and weight (see women's/men's weight at different ages charts at end of section) \* within the last 12 months
  2. Currently receiving triple drug therapy for HIV positive disorder
  3. Continued weight loss despite adequate nutrition and other measures
- Additional 10-week course of Serostim for the treatment of adults with AIDS wasting is considered **medically necessary** if weight loss was arrested during the initial 2-week trial course.
- Continued 12-week courses of Serostim are considered **medically necessary** with documentation of **ALL** of the following:
  1. Weight loss was arrested during the 10-week course that followed the initial 2-week trial course
  2. Individual remains on triple drug therapy for HIV positive disorder
  3. Treatment does not exceed a total of 3 continued 12-week courses
- The following will be reviewed by the clinical pharmacist and/or medical director(s) and/or clinical advisor(s):
  1. Continuation of Serostim for the treatment of adults with AIDS wasting if weight loss is not arrested during the initial 2-week trial course
  2. Additional courses of Serostim for the treatment of adults with AIDS wasting if weight loss has recurred after receiving a 12-week course of therapy



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## GROWTH HORMONE THERAPY (cont.)

**Criteria:** (cont.)

**Serostim:** (cont.)

**AIDS Wasting:** (cont.)

- Continuation of Serostim after 48 weeks of therapy for the treatment of adults with AIDS wasting is considered ***experimental or investigational*** based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.
- Intermittent therapy with Serostim for maintenance in the treatment of adults with AIDS wasting is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

**Other Indications:**

- Serostim for all other indications not previously listed is considered ***experimental or investigational*** based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome.

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**GROWTH HORMONE THERAPY (cont.)**

**Criteria:** (cont.)

**Serostim:** (cont.)

**\*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: under weight    SW: standard weight    OW: over weight

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**GROWTH HORMONE THERAPY (cont.)**

**Criteria:** (cont.)

**Serostim:** (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: under weight    SW: standard weight    OW: over weight

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## GROWTH HORMONE THERAPY (cont.)

**Criteria:** (cont.)

**Zorbtive:**

**Short Bowel Syndrome:**

- Zorbtive for the treatment of adults with short bowel syndrome is considered **medically necessary** for a **single** 4-week course with documentation of concurrent specialized nutritional support (i.e., enteral feedings, parenteral nutrition, fluid and micronutrient supplements).
- Additional course of Zorbtive for the treatment of adults with short bowel syndrome is considered **experimental or investigational** based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome.

**Other Indications:**

- Zorbtive for all other indications not previously listed is considered **experimental or investigational** based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome.



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## GROWTH HORMONE THERAPY (cont.)

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## **GROWTH HORMONE THERAPY (cont.)**

### **Resources:** (cont.)

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17. FDA. FDA Talk Paper: FDA Approves Humatrope for Short Stature. 07/25/2003.
18. FDA. Genotropin Supplement Number 044 Letter. 10/31/2003.
19. FDA. Serostim Supplement 027 Letter. 08/29/2003.
20. Lawson Wilkins Pediatric Endocrine Society, Collett-Solberg, P, Misra, M. Draft Statement Under Development-Working Document: The Role of rhIGF-I in Treating Children with short Stature. Accessed 10/24/2007.
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### FDA Product Approval Information for Serostim:

- FDA-approved indication: For the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Concomitant antiretroviral therapy is necessary.



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## GROWTH HORMONE THERAPY (cont.)

### Resources: (cont.)

FDA Product Approval Information for Tev-Tropin:

- FDA-approved indication: For the treatment of children who have growth failure due to an inadequate secretion of normal endogenous growth hormone.

FDA Product Approval Information for Zorbtive:

- FDA-approved indication: For the treatment of short bowel syndrome in patients receiving specialized nutritional support. Zorbtive therapy should be used in conjunction with optimal management of short bowel syndrome.

Specialized nutritional support may consist of a high carbohydrate, low-fat diet, adjusted for individual patient requirements and preferences. Nutritional supplements may be added according to the discretion of the treating physician. Optimal management of short bowel syndrome may include dietary adjustments, enteral feedings, parenteral nutrition, fluid and micronutrient supplements, as needed.

FDA Product Approval Information for Omnitrope:

- FDA-approved indication: For the treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi Syndrome, Small for Gestational Age, Turner Syndrome and Idiopathic Short Stature.

Treatment of adults with either adult onset or childhood onset GHD.

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## **GROWTH HORMONE THERAPY (cont.)**

### **Resources: (cont.)**

#### FDA Product Approval Information for Humatrope:

- FDA-approved indication: For the treatment of pediatric patients who have growth failure due to inadequate secretion of endogenous growth hormone (GH).

For the treatment of pediatric patients with short stature associated with Turner syndrome.

For the treatment of idiopathic short stature, also called non-GH-deficient short stature, defined by height SDS  $\leq -2.25$  and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients for whom diagnostic evaluation excludes other causes of short stature that should be observed or treated by other means.

For the treatment of short stature or growth failure in children with short stature homeobox-containing gene (SHOX) deficiency.

For the treatment of growth failure in children born small for gestational age (SGA) who fail to demonstrate catch-up growth by age two to four years.

For the replacement of endogenous GH in adults with GH deficiency who meet either of the following two criteria: 1) Adult Onset (AO) patients who have GH deficiency, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma or 2) Childhood Onset (CO) patients who were GH deficient during childhood as a result of congenital, genetic, acquired or idiopathic causes.



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## **GROWTH HORMONE THERAPY (cont.)**

### **Resources:** (cont.)

FDA Product Approval Information for Genotropin:

- FDA-approved indication: For the treatment of children with growth failure due to growth hormone deficiency (GHD).

Treatment of children with Prader-Willi syndrome.

Treatment of children small for gestational age.

Treatment of children with Turner syndrome.

Treatment of children with idiopathic short stature.

Treatment of adults with either adult onset or childhood onset growth hormone deficiency.

FDA Product Approval Information for Norditropin:

- FDA-approved indication: For the treatment of children with growth failure due to growth hormone deficiency (GHD).

Treatment of children with short stature associated with Noonan syndrome.

Treatment of children with short stature associated with Turner syndrome.

Treatment of children with short stature born small for gestational age with no catch-up growth by age 2-4 years.

Treatment of adults with either adult onset or childhood onset growth hormone deficiency.

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## **GROWTH HORMONE THERAPY (cont.)**

### **Resources: (cont.)**

#### FDA Product Approval Information for Nutropin and Nutropin AQ:

- FDA-approved indication: For the treatment of pediatric patients who have growth failure due to inadequate secretion of endogenous growth hormone.

For the treatment of growth failure associated with chronic kidney disease (CKD) up to the time of renal transplantation in pediatric patients. Nutropin therapy should be used in conjunction with optimal management of CKD.

For treatment of short stature associated with Turner syndrome in pediatric patients.

For treatment of idiopathic short stature, also called non-GHD short stature, defined by height SDS  $\leq -2.25$ , 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.

For the replacement of endogenous growth hormone in adults with growth hormone deficiency who meet either of the following two criteria: 1) Adult Onset: Patients who have adult growth hormone deficiency, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma Or 2) Childhood Onset: Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired or idiopathic causes.



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## **GROWTH HORMONE THERAPY (cont.)**

### **Resources: (cont.)**

FDA Product Approval Information for Saizen:

- FDA-approved indication: For the treatment of children with growth failure due to growth hormone deficiency (GHD).

For the treatment of adults with either adult onset or childhood onset GHD.

Genotropin is a registered trademark of Pfizer, Inc., an independent corporation that is not affiliated with BCBSAZ.  
Humatrope is a registered trademark of Eli Lilly, an independent corporation that is not affiliated with BCBSAZ.  
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Tev-Tropin is a registered trademark of Teva Pharmaceuticals, an independent corporation that is not affiliated with BCBSAZ.  
Omnitrope is a trademark of Sandoz, Inc., an independent corporation that is not affiliated with BCBSAZ.