PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**GROWTH HORMONE (GH)***
BRAND NAME	**GENOTROPIN** **HUMATROPE** **NORDITROPIN** **NUTROPIN AQ** **OMNITROPE** **SAIZEN** **ZOMACTON**
(generic)	**(somatropin)**

***Serostim and Zorbtive are not approved for growth hormone deficiency.**

Status: CVS Caremark Criteria ***MDC***
Type: Initial Prior Authorization ***Ref #101-A***

FDA-APPROVED INDICATIONS

Genotropin

Pediatric Patients

Genotropin is indicated for the treatment of:
Pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone (GH).
Pediatric patients who have growth failure due to Prader-Willi syndrome (PWS). The diagnosis of PWS should be confirmed by appropriate genetic testing.
Growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by age 2 years.
Growth failure associated with Turner syndrome.
Idiopathic short stature (ISS), also called non-growth hormone-deficient short stature, defined by height standard deviation score (SDS) ≤-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.

Adult Patients

Genotropin is indicated for replacement of endogenous GH in adults with growth hormone deficiency (GHD) who meet either of the following two criteria:
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 therapy, or trauma; or
Childhood Onset: Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.

Humatrope

Pediatric Patients

Humatrope is indicated for the treatment of:
Pediatric patients who have growth failure due to inadequate secretion of endogenous GH.
Short stature associated with Turner syndrome.
ISS, also called non-GH-deficient short stature, defined by height SDS ≤-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.
Short stature or growth failure in children with short stature homeobox-containing gene (SHOX) deficiency.
Growth failure in children born SGA who fail to demonstrate catch-up growth by age two to four years.

Adult Patients
Humatrope is indicated for the replacement of endogenous GH in adults with GHD who meet either of the following two criteria:
Adult-Onset: 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
Childhood-Onset: Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.

Norditropin
Pediatric Patients
Norditropin is indicated for the treatment of pediatric patients with:
Growth failure due to inadequate secretion of endogenous GH.
Short stature associated with Noonan syndrome.
Short stature associated with Turner syndrome.
Short stature born SGA with no catch-up growth by age 2 to 4 years.

Adult Patients
Norditropin is indicated for the replacement of endogenous GH in adults with GHD who meet either of the following two criteria:
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 therapy, or trauma; or
Childhood Onset: Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.

Nutropin AQ
Pediatric Patients
Nutropin AQ is indicated for the treatment of:
Pediatric patients who have growth failure due to inadequate secretion of endogenous GH.
Growth failure associated with chronic kidney disease (CKD) up to the time of renal transplantation. Nutropin therapy should be used in conjunction with optimal management of CKD.
ISS, also called non-GHD short stature, defined by height SDS ≤-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.
Short stature associated with Turner syndrome.

Adult Patients
Nutropin AQ is indicated for replacement of endogenous GH in adults with GHD who meet either of the following two criteria:
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 therapy, or trauma; or
Childhood Onset: Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.

Omnitrope
Pediatric Patients
Omnitrope is indicated for the treatment of:
Children with growth failure due to inadequate secretion of endogenous GH.
Pediatric patients who have growth failure due to PWS. The diagnosis of PWS should be confirmed by appropriate genetic testing.
Growth failure in children born SGA who fail to manifest catch-up growth by age 2 years.
Growth failure associated with Turner syndrome.
ISS, also called non-GH-deficient short stature, defined by height SDS ≤-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

Adult Patients
Omnitrope is indicated for the replacement of endogenous GH in adults with GHD who meet either of the following two criteria:
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 therapy, or trauma; or
Childhood Onset: Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.

Saizen
Pediatric Patients
Saizen is indicated for the treatment of pediatric patients with growth failure due to inadequate secretion of endogenous GH.

Adult Patients
Saizen is indicated for replacement of endogenous GH in adults with GHD who meet either of the following two criteria:
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 therapy, or trauma; or
Childhood Onset: Patients who were GH deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes.

Zomacton
Zomacton is indicated for the treatment of children who have growth failure due to an inadequate secretion of normal endogenous GH.

Compendial Uses
Human immunodeficiency virus (HIV)-associated wasting/cachexia
Short bowel syndrome (SBS)

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of adult growth hormone deficiency? [If no, skip to question number 3.]	Yes	No
2	Did the patient meet ANY of the following conditions prior to starting treatment: A) Failed 2 pretreatment growth hormone stimulation tests (peak level below 5 ng/mL), B) Structural abnormality of the hypothalamus or pituitary AND 3 or more pituitary hormone deficiencies, C) Childhood-onset growth hormone deficiency with congenital (genetic or structural) abnormality of the hypothalamus/pituitary, D) Failed 1 pretreatment growth hormone stimulation test (peak level below 5 ng/mL) AND low pretreatment insulin-like growth factor-1 (IGF-1) level? [If yes, skip to question number 21.] [If no, no further questions.]	Yes	No
3	Does the patient have a diagnosis of growth failure associated with chronic kidney disease (CKD)? [If yes, skip to question number 20.]	Yes	No
4	Does the patient have a diagnosis of pediatric growth hormone deficiency? [If no, skip to question number 7.]	Yes	No
5	Does the patient meet ONE of the following conditions: A) If younger than 2.5 years of age, pretreatment height more than 2 standard deviations below the mean and slow growth velocity, B) If 2.5 years of age or older, pretreatment 1 year height velocity more than 2 standard deviations below the mean OR pretreatment height more than 2 standard	Yes	No

	deviations below the mean plus a 1 year height velocity more than 1 standard deviation below the mean? [If no, no further questions.]		
6	Does the patient meet ANY of the following conditions: A) Patient failed 2 pretreatment growth hormone stimulation tests (peak level below 10 ng/mL), B) Patient has pituitary or central nervous system disorder (e.g., genetic defect, central nervous system tumor, congenital structural abnormality) AND pretreatment insulin-like growth factor-1 (IGF-1) level more than 2 standard deviations below the mean, C) Patient is a neonate, D) Patient was diagnosed with growth hormone deficiency as a neonate? [If yes, skip to question number 20.] [If no, no further questions.]	Yes	No
7	Does the patient have a diagnosis of Noonan syndrome? [If yes, skip to question number 20.]	Yes	No
8	Does the patient have a diagnosis of idiopathic short stature? [If no, skip to question number 10.]	Yes	No
9	Does the patient meet ALL of the following conditions: A) Pretreatment height more than 2.25 standard deviations below the mean, B) Adult height prediction below 63 inches (5'3") for boys and below 59 inches (4'11") for girls, C) Pediatric growth hormone deficiency has been ruled out by appropriate provocative growth hormone test result of more than 10 ng/mL? [If yes, skip to question number 20.] [If no, no further questions.]	Yes	No
10	Does the patient have a diagnosis of Prader Willi syndrome? [If no, skip to question number 12.]	Yes	No
11	Has the diagnosis been confirmed by one of the following: A) Deletion in the chromosomal 15q11.2-q13 region, B) Maternal uniparental disomy in chromosome 15, C) Imprinting defects or translocations involving chromosome 15? [If yes, skip to question number 21.] [If no, no further questions.]	Yes	No
12	Does the patient have a diagnosis of born small for gestational age (SGA)? [If no, skip to question number 14.]	Yes	No
13	Does the patient meet ALL of the following conditions: A) Patient is at least 2 years of age, B) Birth weight less than 2500 grams at gestational age more than 37 weeks OR a birth weight or length below 3rd percentile or at least 2 standard deviations below the mean for gestational age, C) Did not manifest catch-up growth by age 2? [If yes, skip to question 20.] [If no, no further questions.]	Yes	No
14	Does the patient have a diagnosis of SHOX (short stature homeobox-containing gene) deficiency? [If yes, skip to question number 20.]	Yes	No
15	Does the patient have a diagnosis of Turner syndrome? [If no, skip to question number 18.]	Yes	No
16	Was the diagnosis confirmed by karyotyping? [If no, no further questions.]	Yes	No

17	Is the patient's height less than the 5th percentile for their age? [If yes, skip to question number 20.] [If no, no further questions.]	Yes	No
18	Does the patient have a diagnosis of HIV-associated wasting or cachexia? [If yes, skip to question number 21.]	Yes	No
19	Does the patient have a diagnosis of short bowel syndrome? [If yes, skip to question 21.] [If no, no further questions.]	Yes	No
20	Does the patient have open epiphyses? [If no, no further questions.]	Yes	No
21	Is growth hormone therapy being prescribed by or in consultation with any of the following specialists: A) Endocrinologist, B) Pediatric endocrinologist, C) Geneticist, D) Pediatric nephrologist, E) Infectious disease specialist, F) Gastroenterologist, G) Nutritional support specialist?	Yes	No

Guidelines for Approval							
Duration of Approval				12 months			
Set 1: Adult GHD		Set 2: CKD		Set 3: Pediatric GHD		Set 4: NS	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	None	3	1	4	1	7	1
2		20		5	3	20	3
21		21		6		21	4
				20			
				21			
Set 5: ISS		Set 6: PWS		Set 7: SGA		Set 8: SHOXD	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
8	1	10	1	12	1	14	1
9	3	11	3	13	3	20	3
20	4	21	4	20	4	21	4
21	7		7	21	7		7
			8		8		8
					10		10
							12
Set 9: TS		Set 10: HIV		Set 11: SBS			
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)		
15	1	18	1	19	1		
16	3	21	3	21	3		
17	4		4		4		
20	7		7		7		
21	8		8		8		
	10		10		10		
	12		12		12		
	14		14		14		

			15		15	
					18	

Mapping Instructions		
	Yes	**No**
1.	Go to 2	Go to 3
2.	Go to 21	Deny
3.	Go to 20	Go to 4
4.	Go to 5	Go to 7
5.	Go to 6	Deny
6.	Go to 20	Deny
7.	Go to 20	Go to 8
8.	Go to 9	Go to 10
9.	Go to 20	Deny
10.	Go to 11	Go to 12
11.	Go to 21	Deny
12.	Go to 13	Go to 14
13.	Go to 20	Deny
14.	Go to 20	Go to 15
15.	Go to 16	Go to 18
16.	Go to 17	Deny
17.	Go to 20	Deny
18.	Go to 21	Go to 19
19.	Go to 21	Deny
20.	Go to 21	Deny
21.	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

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DOCUMENT HISTORY

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