

Growth Hormone Injection Prior Authorization Form



**ROCKY MOUNTAIN
HEALTH PLANS®**

We understand Colorado. We understand you.

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____ Pharmacy Phone: _____

Complete the Clinical Assessment:

Diagnosis (check one)	<ul style="list-style-type: none"> • Pediatric: Must provide documentation of <u>growth failure</u> AND: <ul style="list-style-type: none"> <input type="checkbox"/> Inadequate secretion of endogenous growth hormone (GH) <input type="checkbox"/> Prader-Willi Syndrome <input type="checkbox"/> Turner Syndrome <input type="checkbox"/> Small for gestational age who fail to manifest catch-up by age 2 <input type="checkbox"/> Idiopathic short stature (ISS), with height standard deviation score ≤ -2.25 <input type="checkbox"/> Other (please state): _____ • Adult: Must provide documentation of <u>growth hormone deficiency</u> AND: <ul style="list-style-type: none"> <input type="checkbox"/> Adult onset (pituitary disease, hypothalamic disease, surgery, radiation, trauma) <input type="checkbox"/> Child onset (congenital, genetic, acquired, or idiopathic causes) <input type="checkbox"/> Other (please state): _____ <p style="text-align: center;">Please see attached Coverage Policy for more information.</p> <p style="text-align: center;"><i>* For Medicare members, all FDA approved indications will be covered with documentation of growth hormone deficiency (when applicable)</i></p>
	<p style="text-align: center;">Diagnosis: ICD-9 Code #/ Description / J Code (required):</p> <p style="text-align: center;">Please attach a copy of the prescription or provide ALL of the information below:</p> <p>Medication _____</p> <p>Strength _____</p> <p>Sig _____</p> <p>Qty _____</p> <p>Refills _____</p> <p style="text-align: center;">Please attach all relevant medical records and test results.</p> <p style="text-align: center;">Incomplete forms will not be processed.</p>
Supporting Documentation	

I certify that the above is correct and accurate to the best of my knowledge (please sign and date).

STEP
3

Prescriber Signature _____ Date _____

STEP
4

Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk: 970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options.

01/18/11

RMHP Formulary Coverage Policy

Human Growth Hormone

Brand Name	Generic Name
Genotropin	somatropin
Humatrope	somatropin
Norditropin	somatropin
Nutropin	somatropin
Nutropin AQ	somatropin
Omnitrope	somatropin
Saizen*	somatropin
Serostim*	somatropin
Tev-Tropin	somatropin
Zorbtive	somatropin

CLASSIFICATION

Endocrine, metabolic agent
Pituitary hormone, anterior
Human Growth Hormone (hGH)

DESCRIPTION

Endogenous human growth hormone (hGH) is a product of the pituitary gland within the endocrine system. This system produces hormones that are secreted into the blood or lymph and circulated through the body. The hormones released by these glands can have a particular effect on a specific tissue or organ or they can initiate a more general effect manifested through the body. The body's regulation of the release of these hormones through the endocrine system is important for maintaining a proper hormonal balance. Growth hormone has been shown to increase growth by stimulating the production of insulin-like growth factor I (IGF-I), which facilitates cartilage production and its subsequent development into bone, as well as other related proteins. Recombinant human growth hormone is used to increase the growth rate in children with documented growth retardation due to deficiency of growth hormone, to reverse small stature in cases for which growth hormone stimulation has been found beneficial (Hayes Report, October 1996: pg. 1-2).

RATIONALE FOR PRIOR AUTHORIZATION

The intent of the prior authorization (PA) criteria for growth hormone agents is to ensure that patients are appropriately selected and treated according to parameters defined in product labeling, clinical evidence and/or guidelines.

Growth Hormone (GH) has been used for the treatment of childhood GH deficiency (GHD) for over 40 years¹. Historically GH was obtained from cadaver pituitaries and was available in only limited quantities. Today, biosynthetic GH is widely available. Consequently, use in children and adults has increased¹. FDA-approved indications include the treatment of GHD in children and adults with a history of hypothalamic pituitary disease, short stature associated with chronic renal insufficiency before renal transplantation, short stature in patients with Turner Syndrome (TS), Prader-Willi Syndrome (PWS), or Noonan's Syndrome (NS), for the treatment of short stature or growth failure in children with SHOX (short

stature homeobox-containing gene) deficiency, for infants born small for gestational age (SGA) who have not caught up in height, and for children with idiopathic short stature, also termed non-growth hormone-deficient short stature (NGHDSS)²⁻⁹. The FDA has approved Serostim for the treatment of human immunodeficiency virus (HIV)-associated wasting in adults and Zorbtive for patients with Short Bowel Syndrome (SBS) receiving specialized nutritional support.^{10,11} The wide availability and the demonstrated benefits of GH for a variety of evidence based indications have resulted in use of the GH in other conditions for which safety and efficacy have not been established¹.

FORMULARY COVERAGE

Prior authorization (required)

Good Health Formulary: All products are Tier 5 with the exception of:
Nutropin, Nutropin AQ, Saizen, and Serostim which are Tier 4

Commercial Formulary: All products are Tier 6 (medical benefits)

Medicare Part D coverage: All products are Tier 3 (preferred brand)

COVERAGE CRITERIA

(hGH) meets the definition of **medical necessity** for the following:

Table 1. Covered use - Children (≤ 18 years of age)

Diagnosis	Requirement
Prader-Willi Syndrome Turner Syndrome Small for gestational age who fail to manifest catch-up by age 2 Idiopathic short stature (ISS), with height standard deviation score ≤ -2.25	Diagnosis only
AIDS wasting or cachexia	>10% weight loss AND patient actively being treated with antiviral agents
3 rd degree burns	Diagnosis AND will be approved for up to one year after hospitalization for burn
Short bowel syndrome	patient is receiving specialized nutritional support, which may include dietary adjustments, enteral feedings, parenteral nutrition, fluid and micronutrient supplements (Zorbative only)
Chronic renal insufficiency	Patient height more than 2 SD below the mean (less than the 3rd percentile) compared to normal children of same age
Growth Hormone Deficiency	Documented destructive pituitary lesion or GHD as a result of treatment (irradiation, surgery) or trauma OR ALL of the next 3 below Short stature as defined by height more than 2.25 SD below the mean (<3rd percentile) for age and sex AND Growth velocity is <5 cm/year AND Bone age is >2 years behind chronological age AND The patient has failed at least 2 GH stimulation tests (peak GH value of < 10 ng/ml after stimulation)

Table 2. Covered use – Adults (≥ 18 years of age)

Diagnosis	Requirement
Pituitary Disease Hypothalamic disease Cranial surgery Cranial radiation therapy Head trauma Medical history of childhood GHD	Patient has evidence of pituitary disease – may include documented destructive pituitary lesion, GHD as a result of treatment (irradiation, surgery) or trauma, or history of childhood GHD AND Patient has failed two GH stimulation tests (peak GH value of < 5 ng/ml after stimulation) AND The patient has clinical features associated with GH deficiency (e.g., increased abdominal fat mass, decreased lean body mass, decreased muscle mass and strength, decreased exercise capacity, impaired sense of well-being)
AIDS wasting or cachexia	Diagnosis (unexplained weight loss >10% of baseline) AND Patient is being treated with antiviral agents
Third degree burns	Diagnosis only
Short bowel syndrome	Diagnosis AND Patient is receiving specialized nutritional support, which may include dietary adjustments, enteral feedings, parenteral nutrition, fluid and micronutrient supplements

(hGH) is considered **experimental** for the following:

Table 3: Non covered use - Children

Diagnosis	Requirement
SGA (small for gestational age) Constitutional growth delay Partial GH deficiency Neurosecretory GH dysfunction Non-GH-deficient short stature Corticosteroid-induced growth failure Wound healing in burn patients if not 3 rd degree burns Precocious puberty, with GnRH analogues Short stature due to Down's or Noonan's syndrome Obesity Cystic fibrosis Juvenile idiopathic or juvenile chronic arthritis	Not covered – considered experimental or investigational

Table 4. Non-covered use – Adults

Diagnosis	Requirement
Therapy to counter aging effects Anabolic therapy to enhance body mass or strength Anabolic therapy to counteract catabolic illness (not HIV) Wound healing in burn patients if not 3 rd degree burns Altered body habitus from anti-retroviral therapy in HIV Obesity Cystic fibrosis Idiopathic dilated cardiomyopathy	Not covered – considered experimental or investigational

GUIDELINE UPDATE INFORMATION:

This coverage policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered.

All coverage policies are based on FDA approved labeling, research of current medical literature, and review of evidence based medical practice in the treatment and diagnosis of disease.

The purpose of this Rocky Mountain Health Plans coverage policy is to provide a guide to coverage. RMHP coverage policies are not intended to serve as prescribing suggestions or otherwise dictate a particular course of therapy. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.

REFERENCES:

1. AACE Guidelines. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in adults and children 2003 Update. *Endocrine Practice* 2003;9(1):65-76.
2. Genotropin prescribing information. Pharmacia & Upjohn Company. May 2008.
3. Humatrope prescribing information. Eli Lilly and Company. March 2009.
4. Norditropin prescribing information. Novo Nordisk Pharmaceuticals, Inc. September 2008.
5. Nutropin prescribing information. Genentech, Inc. June 2006.
6. Nutropin AQ prescribing information. Genentech, Inc. January 2008.
7. Omnitrope prescribing information. Sandoz Inc. March 2009.
8. Saizen prescribing information. Serono, Inc. October 2007.
9. Tev-Tropin prescribing information. Gate Pharmaceuticals. October
10. Serostim prescribing information. Serono, Inc. September 2007.
11. Zorbtive prescribing information. Serono, Inc. January 2004.