



Somatropin Products
Somatropin Products (HumatroPin, etc) J2941
Prior Authorization Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			
MEMBER INFORMATION			

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known
<input type="checkbox"/> Self-administered <input type="checkbox"/> Provider-administered <input type="checkbox"/> Home Infusion				
<input type="checkbox"/> Chart notes attached. Other important information: _____				
Diagnosis: ICD10: _____ Description: _____				

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Adult growth hormone deficiency, as indicated by ALL of the following

- Clinical findings consisting of 1 or more of the following:
 - Acquired growth hormone deficiency due to 1 or more of the following:
 - Aneurysmal subarachnoid hemorrhage
 - Cranial irradiation
 - Pituitary infarction
 - Pituitary infection
 - Pituitary inflammation
 - Pituitary surgery
 - Pituitary tumor or other tumor within sellar region
 - Traumatic brain or cervical injury
 - Childhood-onset growth hormone deficiency due to 1 or more of the following:

- Known embryopathic lesion (eg, agenesis of corpus callosum, empty sella syndrome, hydrocephalus)
- Known genetic defect associated with HGH deficiency
- Other irreversible structural lesion or damage affecting hypothalamic or pituitary function
- Positive results for stimulated growth hormone testing, as indicated by 1 or more of the following:
 - Peak serum growth hormone concentration less than 5 ng/mL (mcg/L) by insulin tolerance test
 - Peak serum growth hormone concentration less than 0.4 ng/mL (mcg/L) by arginine testing
 - Peak serum growth hormone concentration less than 9 ng/mL (mcg/L) by combined arginine plus growth hormone-releasing hormone (GHRH) testing
 - Peak serum growth hormone concentration less than 1.7 ng/mL (mcg/L) by combined arginine plus L-dopa testing
 - Peak serum growth hormone concentration less than 15 ng/mL (mcg/L) by growth hormone-releasing peptide-2 (GHRP-2) testing
 - Peak serum growth hormone concentration less than 17 ng/mL (mcg/L) by combined GHRP-2 plus GHRH testing
 - Peak serum growth hormone concentration less than 15 ng/mL (mcg/L) by combined GHRP-6 plus GHRH testing
 - Peak serum growth hormone concentration less than 3 ng/mL (mcg/L) by glucagon testing
 - Peak serum growth hormone concentration less than 1.1 ng/mL (mcg/L) by L-dopa testing
 - Peak serum growth hormone concentration less than 5.1 ng/mL (mcg/L) by macimorelin testing
- Other hormone abnormalities, as indicated by ALL of the following:
 - Documented deficiency of at least 3 other pituitary hormones
 - IGF-1 below lower limit of normal for age
- Significant signs or symptoms affecting daily functioning, including 1 or more of the following:
 - Anxiety
 - Atherogenic lipid profile
 - Decreased exercise capacity
 - Decreased lean body mass with increased fat (especially visceral fat)
 - Decreased physical mobility
 - Decreased strength
 - Decreased vitality and energy
 - Depressed mood
 - Disturbances in sexual function
 - Emotional lability
 - Impaired self-control
 - Increased social isolation
 - Osteoporosis or osteopenia
 - Sleep impairment
- No active malignancy
- No acute critical illness
- No proliferative or preproliferative diabetic retinopathy

- Child born small for gestational age (ie, length or weight at least 2 standard deviations below mean for gestational age and gender at birth), as indicated by ALL of the following[E](6)(82)(88)(89)(90)(91):Supporting evidence, suggestions, and alternatives**
 - Age 2 years or older
 - Epiphyses not yet closed
 - Inadequate catch-up growth (ie, height > 2 standard deviations below mean for chronologic age)
 - No active malignancy
 - No acute critical illness
 - No proliferative or preproliferative diabetic retinopathy
- Noonan syndrome, as indicated by ALL of the following:**
 - Epiphyses not yet closed
 - Growth failure with growth deceleration or height 2 std deviations below predicted height for age
 - No active malignancy
 - No acute critical illness
 - No proliferative or preproliferative diabetic retinopathy
 - Optimal nutrition
- Pediatric chronic renal insufficiency, as indicated by ALL of the following:**
 - Chronic renal insufficiency or failure, with glomerular filtration rate less than 75 mL/min/1.73m² (1.25 mL/sec/1.73m²)eGFR
 - Epiphyses not yet closed
 - Growth failure, with decreasing growth curve height percentiles over 6-month period
 - No active malignancy
 - No acute critical illness
 - No proliferative or preproliferative diabetic retinopathy
 - No untreated metabolic condition (eg, acidosis, hypothyroidism, malnutrition, osteodystrophy, salt-wasting disorders)
- Pediatric growth hormone deficiency, as indicated by ALL of the following**
 - Stimulated serum HGH concentrations of less than 10 ng/mL (mcg/L) on 2 or more provocative tests
 - Epiphyses not yet closed
 - Growth rate of -2.5 standard deviations below mean for age
 - No active malignancy
 - No acute critical illness
 - No proliferative or preproliferative diabetic retinopathy
 - No untreated hypothyroidism
- Prader-Willi syndrome and ALL of the following:**
 - Age 18 years or younger
 - Conditions have been ruled out by testing (eg, with arterial blood gases and polysomnography) or are under appropriate treatment, as indicated by ALL of the following:
 - Carbon dioxide level abnormal
 - Central apnea
 - Hypoventilation
 - Obstructive sleep apnea
 - Oxygen saturation abnormal
 - Upper airway obstruction
 - Diagnosis of Prader-Willi syndrome confirmed by genetic testing

- No active malignancy
- No acute critical illness
- No proliferative or preproliferative diabetic retinopathy
- No untreated respiratory infection
- Weight less than 200% of ideal body weight

SHOX gene deficiency and ALL of the following:

- Documentation of genetic abnormality, as indicated by 1 or more of the following:
 - Deletion of one copy of SHOX gene
 - Mutation within or outside one copy of SHOX gene resulting in impaired production or function of SHOX protein
- Epiphyses not yet closed
- Short stature or growth failure
- No active malignancy
- No acute critical illness
- No proliferative or preproliferative diabetic retinopathy

Turner syndrome and ALL of the following:

- Epiphyses not yet closed
- Growth curve is below 5th percentile of normal curve for girls.
- No active malignancy
- No acute critical illness
- No proliferative or preproliferative diabetic retinopathy

Wasting or cachexia associated with AIDS and ALL of the following:

- Age 18 years or older
- AIDS and 1 or more of the following:
 - Decreased exercise capacity affecting daily living
 - Wasting or cachexia
- No active malignancy
- No acute critical illness
- No proliferative or preproliferative diabetic retinopathy
- No other obvious treatable cause(s) for wasting, cachexia, or decreased exercise capacity
- Patient on concomitant antiretroviral therapy

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

- Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

For questions or assistance, please contact Customer Service at 1-877-672-8620, daily, 8am – 8pm (PST) (TTY users should call 1-800-735-2900).

Prior Authorization Group – Somatotropin Agents PA

Drug Name(s):

SOMATROPIN	GENOTROPIN
HUMATROPE	NORDITROPIN
NUTROPIN	TEV-TROPIN
OMNITROPE	GENOTROPIN MINIQUICK
NUTROPIN AQ PEN	

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approvals will be for 12 months

FDA Indications:

Somatotropin Products

- Decreased body growth - Prader-Willi syndrome
- Growth hormone deficiency
- Noonan's syndrome - Short stature disorder
- Renal function impairment with growth failure
- Short stature disorder, Idiopathic
- Short stature disorder, Short-stature homeobox-containing gene (SHOX) deficiency
- Short stature disorder - Turner syndrome
- Small for gestational age baby, with no catch-up growth by age 2 to 4 years

Off-Label Uses:

Somatotropin Products

- Cardiomyopathy
- Crohn's disease
- Diabetic foot ulcer
- Fat maldistribution - HIV infection
- Hyperinsulinism

Age Restrictions:

N/A

Other Clinical Considerations:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/C2EED6/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/B8D798/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Somatropin%2C+E-Coli+Derived&fromInterSaltBase=true&UserMdxSearchTerm=%24userMdxSearchTerm&>false=null&=null#

CLINICAL / CMS
ONLY