MEDICAL POLICY STATEMENT		
Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
06/17/2013	**12/2015**	**12/2014**
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CareSource

CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

A. SUBJECT

- **Somatropin Injection**
  - **Tev-Tropin**
  - **Humatrope**
  - **Omnitrope**
  - **Norditropin– Preferred Product**
  - **Nutropin**
  - **Nutropin AQ**
  - **Saizen**
  - **Serostim**
  - **Genotropin**

B. BACKGROUND

The intent of the somatropin (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. POLICY

CareSource will approve the use of somatropin and consider its use as medically necessary when the following criteria have been met for:

- **Adult HGH deficiency**
- **Child born small for gestational age**
- **Pediatric chronic renal insufficiency**
- **Pediatric HGH deficiency**
- **Prader-Willi syndrome**
- **SHOX gene deficiency**
- **Turner syndrome**
- **Wasting or cachexia associated with AIDS**

All other uses of Somatropin Injection are considered experimental/investigational and therefore, will follow CareSource's off label policy.

- **Adult HGH deficiency** as indicated by **ALL** of the following
  - Prescribed by an endocrinologist or under recommendation of an endocrinologist
  - Clinical findings consisting of **1 or more** of the following:
    - Acquired HGH 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 HGH deficiency due to **1 or more** of the following:
      - Known embryopathic lesion (e.g., 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
    - Peak stimulated serum HGH concentration less than 5 mcg/L
    - Other appropriate 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
    - Decreased exercise capacity
    - Decreased lean body mass with increased 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

- **Child born small for gestational age**, as indicated by **ALL** of the following:

(Excluded for Marketplace members (OH, KY, & IN JUST4ME)

  - Prescribed by an endocrinologist or under recommendation of an endocrinologist
  - Clinical findings consisting of **1 or more** of the following:
    - Length at birth that is 2 standard deviations or more below population average based on gestational age
    - Weight at birth that is 2 standard deviations or more below population average based on gestational age
    - Weight at birth below 10th percentile based on gestational age
  - Child fails to demonstrate catch-up growth, as indicated by **ALL** of the following:
    - Child is 4 years or older
    - Current height velocity standard deviation score less than zero in past year
  - Epiphyses not yet closed

- **Pediatric chronic renal insufficiency**, as indicated by **ALL** of the following):
  - Prescribed by an endocrinologist or under recommendation of an endocrinologist
  - Chronic renal insufficiency or failure, with glomerular filtration rate less than 75 mL/min/1.73m^2 (1.25 mL/sec/1.73m^2) GFR
  - Epiphyses not yet closed
  - Growth failure, with decreasing growth curve height percentiles over 6-month period

- **Pediatric HGH deficiency**, as indicated by **ALL** of the following:
  - Prescribed by an endocrinologist or under recommendation of an endocrinologist
  - Stimulated serum HGH concentrations of less than 10 mcg/L
  - Epiphyses not yet closed
  - Growth rate of minus 2.5 SD below mean for age

- **Prader-Willi syndrome** and **ALL** of the following:
  - Prescribed by an endocrinologist or under recommendation of an endocrinologist
  - Age 18 years or younger
  - Conditions have been ruled out by testing (e.g., 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

- **SHOX gene deficiency** and **ALL** of the following:
  - Prescribed by an endocrinologist or under recommendation of an endocrinologist
  - 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

- **Turner syndrome** and **ALL** of the following:
  - Prescribed by an endocrinologist or under recommendation of an endocrinologist
  - Epiphyses not yet closed
  - Growth curve is below 5th percentile of normal curve for girls

- **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 other obvious treatable cause(s) for wasting, cachexia, or decreased exercise capacity
    - Patient on concomitant antiretroviral therapy

Note: Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

Refer to the product package insert for dosing, administration and safety guidelines.

Please refer to the CareSource policy

Conditions of Coverage

J-Code	J2941
Place Of Service	Office, Outpatient, Home *****Preferred place of service is in the home*.** This medication can be self-administered and can be billed through the pharmacy benefit. **Note:** CareSource supports administering inject able medications in various setting, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.
Authorization Period	Coverage may be initially approved for at least 6 months. Coverage for re-treatment requires meeting current
	policy criteria and evidence of a beneficial response to the growth hormone treatment as shown by growth charts, growth velocity, bone age and recent chart notes. Coverage for growth promotion will cease when the bony epiphyses have closed or when growth velocity slows to below 2.5 cm/yr.

D. REVIEW / REVISION HISTORY

Date Effective: 6/17/2013
Date Revised: 8/2014, 12/2014

E. REFERENCES

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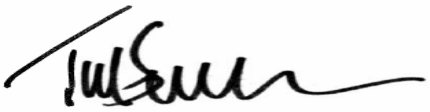
The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

12/2014

Chief Medical Officer **Date**



12/2014

Director of Specialty Pharmacy **Date**