MEDICAL POLICY STATEMENT		
Original Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
06/17/2013	**12/16/2016**	**10/20/2015**
Policy Name		**Policy Number**
Somatropin Injection		**SRx-0048**
Policy Type		
☒ **Medical**	☐ **Administrative**	☐ **Payment**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that 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. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

A. SUBJECT

Somatropin Injection

- Tev-Tropin
- Humatrope
- Onmitrope
- Norditropin
- Nutropin
- Nutropin AQ
- Saizen
- Serostim
- Genotropin
- Zomacton

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. Somatropin is recombinant human growth hormone (hGH) that assists with growth of linear bone, skeletal muscle and organs by stimulating chondrocyte proliferation and differentiation, lipolysis, protein synthesis and hepatic glucose output.

Contraindications for use of hGH include hypersensitivity to growth hormone or any component of the formulation; growth promotion in pediatric patients with closed epiphyses; progression or recurrence of any underlying intracranial lesion or actively growing intracranial tumor; acute critical illness due to complications following open heart or abdominal surgery; multiple accidental trauma or acute respiratory failure; evidence of active malignancy; active proliferative or severe nonproliferative diabetic retinopathy; use in patients with Prader-Willi syndrome without growth hormone deficiency or in patients with Prader-Willi syndrome with growth hormone deficiency

who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment.

C. DEFINITIONS

N/A

D. POLICY

I. CareSource will approve the use of Somatropin and considers its use as medically necessary when the following criteria have been met for:
   A. Adult HGH deficiency
   B. Child born small for gestational age
   C. Pediatric chronic renal insufficiency
   D. Pediatric HGH deficiency
   E. Prader-Willi syndrome
   F. SHOX gene deficiency
   G. Turner syndrome
   H. Wasting or cachexia associate with AIDS
   I. Noonan Syndrome

ALL other uses of Somatropin injection are considered experimental/investigational and therefore, will follow CareSources' Off-Label policy.

II. Adult growth hormone deficiency as indicated by **ALL** of the following:
   A. Prescribed by an endocrinologist
   B. Clinical findings consisting of **1 (one) or more** of the following:
      1. Acquired HGH deficiency due to **1 (one) or more** of the following:
         1.1 Aneurysmal subarachnoid hemorrhage
         1.2 Cranial irradiation
         1.3 Pituitary infarction
         1.4 Pituitary infection
         1.5 Pituitary inflammation
         1.6 Pituitary surgery
         1.7 Pituitary tumor or other tumor within sellar region
         1.8 Traumatic brain or cervical injury
      2. Childhood-onset HGH deficiency due to **1 (one) or more** of the following:
         2.1 Known embryopathic lesion (e.g., agenesis of corpus callosum, empty sella syndrome, hydrocephalus)
         2.2 Known genetic defect associated with HGH deficiency
         2.3 Other irreversible structural lesion or damage affecting hypothalamic or pituitary function
      3. Positive results for stimulated growth testing as indicated by **1 (one) or more** of the following
         3.1 Peak serum growth hormone concentration less than 5 mcg/L by insulin tolerance testing
         3.2 Peak serum growth concentration less than 4 mcg/L by arginine testing
         3.3 peak serum growth hormone concentration less than 3 mcg/L by glucagon testing
      4. Other appropriate hormone abnormalities, as indicated by **ALL** of the following:
         4.1 Documented deficiency of at least **3 (three)** other pituitary hormones
         4.2 IGF-1 below lower limit of normal for age
   C. Significant signs or symptoms affecting daily functioning, including **1 (one) or more** of the following:
      1. Anxiety

2. Atherogenic lipid profile
3. Decreased exercise capacity
4. Decreased lean body mass with increased fat
5. Decreased physical mobility
6. Decreased strength
7. Decreased vitality and energy
8. Depressed mood
9. Disturbances in sexual function
10. Emotional lability
11. Impaired self-control
12. Increased social isolation
13. Osteoporosis or osteopenia
14. Sleep impairment

III. Child born small for gestational age, as indicated by **ALL** of the following:
(Excluded for Marketplace members: JUST4ME)
   A. Prescribed by an endocrinologist
   B. Clinical findings consisting of **1 (one) or more** of the following:
      1. Length at birth that is 2 (two) standard deviations or more below population average based on gestational age
      2. Weight at birth that is 2 (two) standard deviations or more below population average based on gestational age
      3. Weight at birth below 10^{th} percentile based on gestational age
   C. Child fails to demonstrate catch-up growth, as indicated by **ALL** of the following:
      1. Child is 4 (four) years or older
      2. Current height velocity standard deviation score less than zero in past year
   D. Epiphyses not yet closed

IV. Pediatric chronic renal insufficiency, as indicated by **ALL** of the following:
   A. Prescribed by an endocrinologist
   B. Chronic renal insufficiency or failure, with glomerular filtration rate less than 75 mL/min/1.73m^2 (1.25 mL/sec/1.73m^2)
   C. Epiphyses not yet closed
   D. Growth failure, with decreasing growth curve height percentiles over 6-month period
   E. No untreated metabolic condition (acidosis, hypothyroidism, malnutrition, osteodystrophy, salt-wasting disorders)

V. Pediatric growth hormone deficiency, as indicated by **ALL** of the following:
   A. Prescribed by an endocrinologist
   B. Stimulated serum HGH concentrations of less than 10 mcg/L
   C. Epiphyses not yet closed
   D. Growth rate of minus 2.5 SD below mean for age
   E. No untreated hypothyroidism

VI. Prader-Willi syndrome and **ALL** of the following:
   A. Prescribed by an endocrinologist
   B. Age 18 years or younger
   C. 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:
      1. Carbon dioxide level abnormal
      2. Central apnea

3. Hypoventilation
4. Obstructive sleep apnea
5. Oxygen saturation abnormal
6. Upper airway obstruction

D. Diagnosis of Prader-Willi syndrome confirmed by genetic testing
E. No untreated respiratory infection
F. Weight less than 200% of ideal body weight (not obese)

VII. SHOX gene deficiency and **ALL** of the following:
A. Prescribed by an endocrinologist
B. Documentation of genetic abnormality, as indicated by **1 (one) or more** of the following:
1. Deletion of one copy of SHOX gene
2. Mutation within or outside one copy of SHOX gene resulting in impaired production or function of SHOX protein
C. Epiphyses not yet closed
D. Short stature or growth failure

VIII. Turner syndrome and **ALL** of the following:
A. Prescribed by an endocrinologist
B. Epiphyses not yet closed
C. Growth curve is below 5th percentile of normal curve for girls

VIII. Wasting or cachexia associated with AIDS and **ALL** of the following:
A. Age 18 years or older
B. AIDS and **1 (one) or more** of the following:
1. Decreased exercise capacity affecting daily living
2. Wasting or cachexia
C. No other obvious treatable cause(s) for wasting, cachexia, or decreased exercise capacity
D. Patient on concomitant antiretroviral therapy

IX. Noonan syndrome as indicated by **ALL** of the following
A. Epiphyses not yet closed
B. Growth failure with growth deceleration or height 2 standard deviations below predicted height for age
C. Optimal nutrition

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 are not limited to test reports; chart notes form provider's office or hospital admission notes.

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

CONDITIONS OF COVERAGE
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 injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective settings 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 nay required monitoring or additional services that may coincide with the delivery of the specific medication.

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Step Therapy
Under some plans, including plans that use an open or closed formulary, some of the medications in this policy may be subject to step-therapy. Refer to the CareSource formulary tool or PDL for further guidance.

AUTHORIZATION PERIOD
Coverage may be initially approved for at least 6 (six) 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 continue when growth velocity is at least 2.5 cm/yr. or for children over 12 years old either an X-ray report shows epiphyses have not closed or a Sexual Maturity Rating (SMR, Tanner Stage) is less than or equal to 3.

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued:	06/17/2013
Date Reviewed:	06/17/2013, 08/17/2014, 12/16/2014, 10/20/2015
Date Revised:	08/17/2014, 12/16/2014 10/20/2015 - added detail to reauth criteria

G. REFERENCES

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This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

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