PHARMACY POLICY STATEMENT

Original Effective Date	Next Annual Review	Last Revision
06/17/2013	12/16/2017	11/29/2016
Policy Name		**Policy Number**
Somatropin Injection		SRx-0070
Policy Type		
Medical	Administrative	**PHARMACY**	Reimbursement

Pharmacy 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, Pharmacy Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Pharmacy 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 Pharmacy Policy Statement. If there is a conflict between the Pharmacy 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

Contents of Policy

A. INTRODUCTION

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our patients with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

NOTE: The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.

B. DEFINITIONS

1. None applicable.

C. POLICY COVERAGE CRITERIA

1. Site of Service

Site of Service Administration	Coverage Criteria
Office, Outpatient, Home	**Preferred place of service is in the home.** **These medications can be self-administered and can be billed through the pharmacy benefit.** 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(s) and unique needs and condition(s). The decision on the most appropriate setting for administration is based on the member's current medical condition(s) and any required monitoring or additional services that may coincide with the delivery of the specific medication.

2. Coverage Criteria

CareSource will approve the use of Genotropin, Humatrope, Norditropin, Nutropin AQ, Onmitrope, Saizen, Serostim and Tev-Tropin and consider use medically necessary when the criteria have been met for each condition listed

below. Prior authorization request should be submitted with chart notes and documentation supporting medical necessity.

Condition	Omnitrope Vial Coverage criteria:
Adult Growth Hormone Deficiency (GHD)	1) Prescribed by an endocrinologist 2) Clinical findings consisting of one or more of the following: a) Acquired human growth hormone (HGH) deficiency due to pituitary disease or a condition affecting pituitary function. b) Childhood-onset HGH deficiency 3) Diagnosis of GHD confirmed by ONE of the following: a) Peak serum growth hormone concentration < 5 mcg/L by insulin tolerance testing b) Peak serum growth concentration < 3.1 mcg/L by glucagon stimulation testing c) Documented deficiency of at least 3 other pituitary hormones d) One pituitary hormone deficiency (other than growth hormone) and one of following: i) Peak serum growth hormone concentration less than 5 mcg/L by insulin tolerance testing ii) Peak serum growth concentration < 3.1 mcg/L by glucagon stimulation testing
Pediatric chronic renal insufficiency	1) Prescribed by an endocrinologist 2) Chronic renal insufficiency or failure, with glomerular filtration rate less than 75 mL/min/1.73m^2 (1.25 mL/sec/1.73m^2) 3) Epiphyses not yet closed
Pediatric growth hormone deficiency	1) Prescribed by an endocrinologist 2) Epiphyses not yet closed 3) Growth rate of minus 2.5 SD below mean for age 4) GHD is confirmed by one of the following: a) Two growth hormone stimulation test below 10 mg/ml b) Documented presence of at least two other pituitary hormone deficiencies and Insulin-like growth factor 1 (IGF-1) measurement below age-appropriate level c) Neonate with hypoglycemia and growth hormone level of less than 10 ng/ml d) One growth hormone stimulation test below 10 mg/ml and a pituitary disease or a condition affecting pituitary function

Condition	Omnitrope Vial Coverage criteria (continued):
Prader-Willi syndrome	1) Prescribed by an endocrinologist 2) Age 18 years or younger 3) Diagnosis of Prader-Willi syndrome confirmed by genetic testing 4) One growth hormone stimulation test below 10 mg/ml
Wasting or cachexia associated with AIDS	1) Age 18 years or older 2) Greater than 10% of baseline weight loss 3) Patient on concomitant antiretroviral therapy

Condition	Genotropin, Humatrope, Norditropin, Nutropin AQ, Onmitrope Pen, Saizen, Serostim, and Tev-Tropin Coverage criteria:
Adult Growth Hormone Deficiency	1) Prescribed by an endocrinologist 2) Clinical findings consisting of 1 (one) or more of the following: a) Acquired HGH deficiency due to pituitary disease or a condition affecting pituitary function. b) Childhood-onset HGH deficiency 3) Diagnosis of GHD confirmed by ONE of the following: a) Peak serum growth hormone concentration < 5 mcg/L by insulin tolerance testing b) Peak serum growth concentration < 3.1 mcg/L by glucagon stimulation testing c) Documented deficiency of at least 3 other pituitary hormones d) One pituitary hormone deficiency (other than growth hormone) and one of following: i) Peak serum growth hormone concentration less than 5 mcg/L by insulin tolerance testing ii) Peak serum growth concentration < 3.1 mcg/L by glucagon stimulation testing 4) A minimum of a 30 day trial of Omnitrope Vial, and documented clinical reason why another agent must be used.

Condition	Genotropin, Humatrope, Norditropin, Nutropin AQ, Onmitrope Pen, Saizen, Serostim, and Tev-Tropin Coverage criteria (continued):
Pediatric chronic renal insufficiency	1) Prescribed by an endocrinologist 2) Chronic renal insufficiency or failure, with glomerular filtration rate less than 75 mL/min/1.73m^2 (1.25 mL/sec/1.73m^2) 3) Epiphyses not yet closed 4) A minimum of a 30 day trial of Omnitrope Vial, and documented clinical reason why another agent must be used.
Pediatric growth hormone deficiency	1) Prescribed by an endocrinologist 2) Epiphyses not yet closed 3) Growth rate of minus 2.5 SD below mean for age 4) Growth hormone deficiency is confirmed by one of the following: a. Two growth hormone stimulation test below 10 mg/ml b. Documented presence of at least two other pituitary hormone deficiencies and Insulin-like growth factor 1 (IGF-1) measurement below age-appropriate level c. Neonate with hypoglycemia and growth hormone level of less than 10 ng/ml d. One growth hormone stimulation test below 10 mg/ml and a pituitary disease or a condition affecting pituitary function 5) A minimum of a 30 day trial of Omnitrope Vial, and documented clinical reason why another agent must be used.
Prader-Willi syndrome	1) Prescribed by an endocrinologist 2) Age 18 years or younger 3) Diagnosis of Prader-Willi syndrome confirmed by genetic testing 4) One growth hormone stimulation test below 10 mg/ml 5) A minimum of a 30 day trial of Omnitrope Vial, and documented clinical reason why another agent must be used.
Wasting or cachexia associated with AIDS	1) Age 18 years or older 2) Greater than 10% of baseline weight loss 3) Patient on concomitant antiretroviral therapy 4) A minimum of a 30 day trial of Omnitrope Vial, and documented clinical reason why another agent must be used.

Please note that this policy is reviewed on an annual basis. New drugs and indications receiving FDA approval may not be reflected in this policy immediately.

Notes:

- Documented diagnosis must be confirmed by portions of the individual's medical record which need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office, or hospital admission notes.
- Patient is required to have completed the trial(s) listed in the above criteria unless the patient is unable to tolerate or has a contraindication to trial medications. Documentation such as chart notes or pharmacy claims may be requested to verify trial(s), intolerance, or contraindication(s).
- Refer to the product package insert for dosing, administration and safety guidelines.

3. Dosage and Quantity Limits (listed if applicable)

Information for patients with renal or hepatic impairment is not included. See package insert for individual agents.

Drug	Dosage and Quantity Limits
Genotropin/Omnitrope	0.08 mg/kg/week
Humatrope	0.0125 mg/kg/day
Norditropin	0.016 mg/kg/day
Nutropin/Nutropin AQ	0.025 mg/kg/day in patients 35 years and younger; 0.0125 mg/kg/day in patients older than 35 years
Saizen	0.01 mg/kg/day
Serostim	6 mg/day

4. Authorization Period

Condition	Approval Period
Pediatric growth hormone deficiency	The initial authorization of Genotropin, Humatrope, Norditropin, Nutropin AQ, Onmitrope, Saizen, Serostim or Tev-Tropin is valid for 1 year. Continued treatment may be considered for **Pediatric growth hormone deficiency** 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. Males 16 years or older or females 14 years or older need to reconfirm the growth hormone deficiency with one of the following: two growth hormone stimulation test below 10 mg/ml, documented presence of at least two other pituitary hormone deficiencies and Insulin-like growth factor 1 (IGF-1)

	measurement below age-appropriate level, neonate with hypoglycemia and growth hormone level of less than 10 ng/ml or one growth hormone stimulation test below 10 mg/ml and a pituitary disease or a condition affecting pituitary function. A reauthorization after successful initiation period will be placed for 1 year. **ALL** authorizations are subject to continued eligibility.
Adult growth hormone deficiency **Pediatric chronic renal insufficiency** **Prader-Willi syndrome** **Wasting or cachexia associated with AIDS**	The initial authorization of Genotropin, Humatrope, Norditropin, Nutropin AQ, Onmitrope, Saizen, Serostim or Tev-Tropin is valid for 1 year. Continued treatment may be considered when patient meets current policy criteria and evidence of a beneficial response to the growth hormone treatment. A reauthorization after successful initiation period will be placed for 1 year. **ALL** authorizations are subject to continued eligibility.

5. Coding

Not applicable – covered on pharmacy benefit

D. RELATED POLICIES

None applicable.

E. REVIEW/REVISION HISTORY

DATE	ACTION/DESCRIPTION
6/17/2013	Policy created
10/20/2015	Added reauthorization criteria
11/29/2016	Updated criteria and policy format

F. REFERENCES

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The Pharmacy Policy detailed above has received due consideration and is approved.

Independent medical review – 12/12/2016