MEDICATION POLICY

Generic Name: Somatropin (Adult)

Therapeutic Class or Brand Name: Growth Hormone (Adult)

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Genotropin®, Norditropin®.

Non-preferred: Humatrope®, Nutropin AQ®, Omnitrope®, Saizen®, Serostim®, Zomacton™, and Zorbtive®.

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 2/12/18

GPI Code: 3010002000, 3010002010

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:

A. Growth hormone deficiency and ONE of criteria 1 OR 2 is met:

1. One pituitary hormone deficiency (other than growth hormone) requiring hormone replacement (such as TSH, ACTH, gonadotropins, and ADH) AND both of the following criteria a AND b are met:

a. At least one known cause for pituitary disease or a condition affecting pituitary function, including pituitary tumor, surgical damage, hypothalamic disease, irradiation, trauma, panhypopituitarism, or infiltrative diseases (histoplasmosis, Sheehan syndrome, autoimmune hypophysitis, or sarcoidosis) is documented.

b. ONE growth hormone provocative stimulation test (with insulin, levodopa, arginine, propranolol, clonidine, or glucagon) with a measured peak level of less 5 ng/ml.

2. Three pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement AND an IGF-1 level below 80 ng/ml.

B. Short Bowel Syndrome and criteria 1 through 3 are met:

1. Ability to ingest solid food.

2. Dependent on parenteral nutrition at least five days per week to provide at least 3,000 calories per week.

3. Chart notes to indicate dietary needs and goals have been addressed.

C. AIDS Wasting Syndrome and criteria 1 through 4 are met:

1. Documented diagnosis of AIDS.
2. Patient must be taking antiretroviral medications.
3. Documented weight loss of at least 10% from baseline weight OR a body mass index (BMI) of less than 20.
4. Documentation that the patient has had an adequate nutritional evaluation and has failed to respond adequately to a high calorie diet.

II. Prescriber is an endocrinologist, gastroenterologist, or infectious disease specialist.

III. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

Exclusion Criteria:

- Acute Critical Illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma, or those with acute respiratory failure.
- Active Malignancy.
- Active Proliferative or Severe Non-Proliferative Diabetic Retinopathy.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- The quantity is limited to a maximum of a 30 day supply per fill.

Approval Length:

- **Authorization:**
  - Short bowel syndrome: One time for up to 4 weeks.
  - AIDS related wasting: Up to 12 weeks.
  - Growth hormone deficiency: Up to 12 months.
- **Re-Authorization:**
  - Short bowel syndrome: N/A

- AIDS related wasting: An additional 12 weeks of therapy may be approved in patients who still meet current medical necessity criteria and demonstrate weight gain with the initial 12 weeks of therapy.
- Growth hormone deficiency: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/GrowthHormoneAIDS.pdf.
2. http://blue.regence.com/trgmedpol/drugs/dru015.pdf.
3. https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/growth-hormone-replacement-therapy-pmng.
4. Medi-Span.
5. http://labeling.pfizer.com/ShowLabeling.aspx?id=577.
6. http://uspl.lilly.com/humatrope/humatrope.html#pi.
7. http://www.novo-pi.com/norditropin.pdf.
8. http://www.gene.com/download/pdf/nutropin_aq_PI.pdf.
9. http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=58d84ffa-4056-4e36-ad67-7bd4aef444a5.
10. http://www.emdserono.com/cmg.emdserono_us/en/images/saizen.ce.pi_tcm115_19400.pdf?Version=.
11. http://www.emdserono.com/ms.country.us/en/images/Serostim_PI_tcm115_140011.pdf.
12. http://www.ferringusa.com/wp-content/uploads/2017/01/ZomactonPI-9.2016.pdf.
13. http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c04b1b2c-5484-4a5d-887a-3f7ace8388a1.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
2/12/2018	1. **Changed** "Non-preferred: Genotropin®" **to** "Preferred: Genotropin®" **under Applicable Drugs**.
9/15/2017	1. **Changed** "Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Serostim®, Zomacton™, and Zorbtive®" **to** "Preferred: Norditropin®; Non-preferred: Genotropin®, Humatrope®, Nutropin AQ®, Omnitrope®, Saizen®, Serostim®, Zomacton™, and Zorbtive®" **under Applicable Drugs**. 2. **Added** "III. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s)" **under Prior Authorization Criteria**. 3. **Updated** "http://www.emdserono.com/cmg.emdserono_us/en/images/Serostim_PI_tcm115_19402.pdf?Version=" **to** "http://www.emdserono.com/ms.country.us/en/images/Serostim_PI_tcm115_140011.pdf" **and** "http://www.ferringusa.com/ZomactonPI.pdf" **to** "http://www.ferringusa.com/wp-content/uploads/2017/01/ZomactonPI-9.2016.pdf" **under References**.
5/21/2016	1. **Changed** "Nutropin®/Nutropin AQ®" **to** "Nutropin AQ®" **under Applicable Drugs**. 2. **Removed** "9705105010" **from list following GPI Code**. 3. **Changed the following under Prior Authorization Criteria:** - "A. Growth hormone deficiency with panhypopituitarism…" **to** "A. Growth hormone deficiency…". - "A1a…. trauma, or infiltrative diseases…" **to** "A1a…. trauma, panhypopituitarism, or infiltrative diseases…". - "A1b. ONE provocative stimulation test of less than 5 ng/ml. The insulin tolerance test is the preferred testing method, but other secretagogues, such as arginine, GHRH, clonidine and L dopa are acceptable" **to** "A1b. ONE growth hormone provocative stimulation test (with insulin, levodopa, arginine, propranolol, clonidine, or glucagon) with a measured peak level of less 5 ng/ml". - "C1. A documented diagnosis of AIDS" **to** "Documented diagnosis of AIDS". - "C3. A weight loss of at least…" **to** "C3. Documented weight loss of at least…". 4. **Removed** "II. Minimum age requirement: 18 years old" **from Prior Authorization Criteria**. 5. **Updated** "http://pi.lilly.com/us/humatrope-cart-pi.pdf" **to** "http://uspl.lilly.com/humatrope/humatrope.html#pi" **and** "http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/Recombinate_HGH_Therapy.pdf" **to** "https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/growth-hormone-replacement-therapy-pmng" **under References**. 6. **Added** "http://www.ferringusa.com/ZomactonPI.pdf" **under References**. 7. **Removed** "http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=936aec5f-3fa9-561b-1875-862f21057b95" **and** "http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=e6574a25-1ad5-4946-b750-501ce745574f" **under References** (links no longer valid).
9/28/2015	1. **Changed** "Preferred: Tev-Tropin®; Non-preferred: Genotropin®, Humatrope®, Norditropin®, Nutropin®/Nutropin AQ®, Omnitrope®, Saizen®, Serostim®, and Zorbtive®" **to** "Genotropin®, Humatrope®, Norditropin®, Nutropin®/Nutropin AQ®, Omnitrope®, Saizen®, Serostim®, Zomacton™, and Zorbtive®" **under Applicable Drugs**. 2. **Removed** "Non-preferred products require a documented trial and failure of or contraindication to the preferred product" **from Prior Authorization Criteria**.
5/13/2015	1. **Changed** "Non-preferred products require a documented trial and failure of or contraindication to the preferred product (Tev-Tropin®)" **to** "Non-preferred products require a documented trial and failure of or contraindication to the preferred product" **under Prior Authorization Criteria**. 2. **Changed** "Acute Critical Illness" **to** "Acute Critical Illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma, or those with acute respiratory failure" **under Exclusion Criteria**.

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	3. **Changed** "Diabetic Retinopathy" **to** "Active Proliferative or Severe Non-Proliferative Diabetic Retinopathy" **under Exclusion Criteria**. 4. **Changed** "Short bowel syndrome: Up to 4 weeks. No further authorization shall be given" **to** "Short bowel syndrome: One time for up to 4 weeks" **under Authorization under Approval Length**. 5. **Changed** "Short bowel syndrome: No further authorization shall be given" **to** "Short bowel syndrome: N/A" **under Re-Authorization under Approval Length**. 6. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Growth_Hormone_AIDS.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/GrowthHormoneAIDS.pdf", "http://www.tev-tropin.com/pdf/Tev-Tropin-PI.pdf" **to** "http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=936aec5f-3fa9-561b-1875-862f21057b95", "http://www.serostim.com/files/pdfs/SEROSTIM_PI.pdf" **to** "http://www.emdserono.com/cmg.emdserono_us/en/images/Serostim_PI_tcm115_19402.pdf?Version=", **and** "http://www.emdserono.com/cmg.emdserono_us/en/images/PI%20Zorbtive%208.8mg_HCP_Jan12_tcm115_105820.pdf?Version=" **to** "http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c04b1b2c-5484-4a5d-887a-3f7ace8388a1" **under References**.
1/31/2014	1. **Adapted policy to new format.** 2. **Changed Generic Name from** "Somatropin (Adult - AIDS)" **to** "Somatropin (Adult)". 3. **Changed Therapeutic Class or Brand Name from** "Growth Hormone (Adult - AIDS)" **to** "Growth Hormone (Adult)". 4. **Changed Applicable Drugs from** "Serostim® (somatropin)" **to** "Preferred: Tev-Tropin®; Non-preferred: Genotropin®, Humatrope®, Norditropin®, Nutropin®/Nutropin AQ®, Omnitrope®, Saizen®, Serostim®, and Zorbtive®". 5. **Added GPI Codes**. 6. **Changed Prior Authorization Criteria from**: "Documented diagnosis of Adult onset - AIDS Wasting indication only; Body Mass Index is less than 20, BMI = wt times 704 divided by height squared (in inches); Patient must be taking antiretroviral medications; Rule out causes of weight loss including hypogonadism, opportunistic infections, diarrhea, inadequate nutritional intake, malabsorption, and thyroid abnormalities; (For men) Rule out hypotestosterone levels since hypogonadism is common among HIV infected individuals; Patient must be able to maintain 100% of daily nutritional intake. For patients receiving enteral or parenteral nutrition, the patient must be weight stable for two months; Patient must not have an untreated or suspected systemic infection or persistent fever > 101 F during the 30 days prior to evaluation of weight loss; Patient must not have any signs or symptoms of gastrointestinal malabsorption or blockage unless on total parenteral nutrition; Patient must not have active malignancy, except for Kaposi's Sarcoma (KS); Minimum age requirement: 19 years old" **to:** "I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis: A. Growth hormone deficiency with panhypopituitarism and ONE of criteria 1 OR 2 is met: 1. One pituitary hormone deficiency (other than growth hormone) requiring hormone replacement (such as TSH, ACTH, gonadotropins, and ADH) AND both of the following criteria a AND b are met: a. At least one known cause for pituitary disease or a condition affecting pituitary function, including pituitary tumor, surgical damage, hypothalamic disease, irradiation, trauma, or infiltrative diseases (histoplasmosis, Sheehan syndrome, autoimmune hypophysitis, or sarcoidosis) is documented; b. ONE provocative stimulation test of less than 5 ng/ml. The insulin tolerance test is the preferred testing method, but other secretagogues, such as arginine, GHRH, clonidine and L dopa are acceptable. 2. Three pituitary hormone deficiencies (other than growth hormone) requiring hormone replacement AND an IGF-

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	1 level below 80 ng/ml; B. Short Bowel Syndrome and criteria 1 through 3 are met: 1. Ability to ingest solid food; 2. Dependent on parenteral nutrition at least five days per week to provide at least 3,000 calories per week; 3. Chart notes to indicate dietary needs and goals have been addressed; C. AIDS Wasting Syndrome and criteria 1 through 4 are met: 1. A documented diagnosis of AIDS; 2. Patient must be taking antiretroviral medications; 3. A weight loss of at least 10% from baseline weight OR a body mass index (BMI) of less than 20; 3. Documentation that the patient has had an adequate nutritional evaluation and has failed to respond adequately to a high calorie diet; II. Minimum age requirement: 18 years old; III. Prescriber is an endocrinologist, gastroenterologist, or infectious disease specialist; III. Non-preferred products require a documented trial and failure of or contraindication to the preferred product (Tev-Tropin®)". 7. **Changed Exclusion Criteria from** "N/A" **to** "Acute Critical Illness; Active Malignancy; Diabetic Retinopathy". 8. **Added** "The quantity is limited to a maximum of a 30 day supply per fill" **under Quantity/Days Supply Restrictions**. 9. **Changed Authorization under Approval Length from** "Initial trial 60 days" **to** "Short bowel syndrome: Up to 4 weeks. No further authorization shall be given; AIDS related wasting: Up to 12 weeks; Growth hormone deficiency: Up to 12 months". 10. **Changed Re-Authorization under Approval Length from** "Fax copy of current prescription and history and physical showing weight gain during trial period. With appropriate progress, the patient may receive an additional four weeks of therapy. If the patient continues to show progress, additional prior authorizations are granted in six week periods only to a maximum of twelve weeks per any six month episode" **to:** "Short bowel syndrome: No further authorization shall be given; AIDS related wasting: An additional 12 weeks of therapy may be approved in patients who still meet current medical necessity criteria and demonstrate weight gain with the initial 12 weeks of therapy; Growth hormone deficiency: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective". 11. **Updated references** to include Regence policy, Tufts policy, Medi-Span, and package inserts.