MEDICATION POLICY

Generic Name: Somatropin (Children)

Therapeutic Class or Brand Name: Growth Hormone (Children)

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 G AND must meet criteria listed under applicable diagnosis:

A. Growth hormone deficiency (GHD) and criteria 1 through 3 are met:

1. Documented biochemical growth hormone deficiency by meeting ONE of criteria a through e:
   a. Two growth hormone (GH) stimulation tests below 10 ng/ml (microgram/L).
   b. At least one GH stimulation test level less than 15 ng/ml, AND IGF-l and IGF-BP3 levels below normal for the patient's bone age and gender.
   c. One GH stimulation test below 10 ng/ml (microgram/L) is sufficient for children with defined CNS pathology, history of irradiation, or genetic conditions associated with GHD.
   d. GH stimulation tests, IGF-1 or IGF-BP3 levels are not needed for GHD if multiple pituitary hormone deficiencies exist (at least two other in addition to GHD).
   e. GH stimulation tests, IGF-1 or IGF-BP3 levels are not needed for congenital GHD (low GH levels detected during acute episode of hypoglycemia).
2. Must provide an initial bone age and demonstration of open growth plates.
3. Documented short stature/growth failure (subnormal growth rate) by meeting ONE of criteria a, b, OR c:
   a. Height is below the 3rd percentile for the patient's age and gender.

b. Height is below the 5th percentile for the patient's age and gender, and untreated growth velocity with a minimum of 1 year of growth data is below the 25th percentile for the patient's age and gender.

c. If GHD criteria under 1e are met, short stature/growth failure is not needed.

B. Growth failure due to Prader-Willi Syndrome (PWS) and criteria 1 and 2 are met:

1. Documentation that the diagnosis of PWS has been confirmed by appropriate genetic testing.
2. Must provide an initial bone age and demonstration of open growth plates.

C. Growth failure in children born small for gestational age (SGA) who fail to demonstrate catch-up growth by age 2 to 4 years and criteria 1 through 5 are met:

1. Documentation that patient was born SGA, defined as a birth weight and/or length of 2 or more standard deviations below the mean for gestational age and gender (including infants born with intrauterine growth restriction or Russell-Silver Syndrome resulting in SGA).
2. Documented short stature/growth failure (subnormal growth rate) by 2 years of age when height is 2 or more standard deviations below the mean for the patient's age and gender.
3. Documentation that other causes for short stature such as growth inhibiting medication, endocrine disorders, and emotional deprivation or syndromes have been ruled out.
4. Must provide an initial bone age and demonstration of open growth plates.
5. Minimum age requirement: 2 years old.

D. Growth failure associated with Turner's or Noonan's Syndrome and criteria 1 and 2 are met:

1. Must provide an initial bone age and demonstration of open growth plates.
2. Documented short stature/growth failure (subnormal growth rate) when height is below the 10^{th} percentile for the patient's age and gender.

E. Short stature or growth failure in children with short stature homeobox-containing gene (SHOX) deficiency and criteria 1 and 2 are met:

1. Must provide an initial bone age and demonstration of open growth plates.
2. Documented short stature/growth failure (subnormal growth rate) when height is at least 2 standard deviations below the normal mean for the patient's age and gender.

F. Growth failure associated with Chronic renal insufficiency (CRI) and criteria 1 through 3 are met:

1. Must provide an initial bone age and demonstration of open growth plates.

2. Documented short stature/growth failure (subnormal growth rate) when height is below the 5th percentile for the patient's age and gender, and untreated growth velocity with a minimum of 1 year of growth data is below the 25th percentile for the patient's age and gender.
3. Patient requires weekly dialysis or has a glomerular filtration rate (GFR) < 75 ml/min / 1.73 m2.

G. Pediatric burn patients and criterion 1 is met:

1. Burns are over at least 40% of the total body surface area.

II. Prescriber is a pediatric endocrinologist, pediatric nephrologist, or trauma/burn surgeon.

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.
- Children with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment.
- Active Malignancy.
- Active Proliferative or Severe Non-Proliferative Diabetic Retinopathy.
- Children with closed epiphyses.

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:**
  - Pediatric burn: One time for up to 12 months.
  - All other diagnoses: Up to 12 months or until maximum bone age is met (up to 16 years of age for males or 14 years of age for females), whichever is shorter.
- **Re-Authorization:**

- Pediatric burn: N/A
- All other diagnoses: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the patient's growth velocity is greater than 2.5 cm/year. Must also include documentation of a through b below, if applicable:
  a. Bone age must be obtained annually when chronological age reaches 15 in males or 13 in females. Therapy must not exceed a bone age of 16 in males or 14 in females.
  b. If diagnosis is chronic renal insufficiency (CRI), patient must still require weekly dialysis or have a glomerular filtration rate (GFR) < 75 ml/min / 1.73 m2.

Appendix:

N/A

References:

1. https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/GrowthHormone.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. https://secured.connecticare.com/providers/PDFs/Pharmacy/Growth%20Hormone.pdf.
5. Medi-Span.
6. http://labeling.pfizer.com/ShowLabeling.aspx?id=577.
7. http://uspl.lilly.com/humatrope/humatrope.html#pi.
8. http://www.novo-pi.com/norditropin.pdf.
9. http://www.gene.com/download/pdf/nutropin_aq_PI.pdf.
10. http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=58d84ffa-4056-4e36-ad67-7bd4aef444a5.
11. http://www.emdserono.com/cmg.emdserono_us/en/images/saizen.ce.pi_tcm115_19400.pdf?Version=.
12. http://www.emdserono.com/ms.country.us/en/images/Serostim_PI_tcm115_140011.pdf.
13. http://www.ferringusa.com/wp-content/uploads/2017/01/ZomactonPI-9.2016.pdf.
14. http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c04b1b2c-5484-4a5d-887a-3f7ace8388a1.

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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** "https://www.connecticare.com/provider/PDFs/Pharmacy/Growth%20Hormone%20New.pdf" **to** "https://secured.connecticare.com/providers/PDFs/Pharmacy/Growth%20Hormone.pdf"**,** "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. **Added the following under Prior Authorization Criteria:** - "C. Growth failure in children born small for gestational age (SGA) who fail to demonstrate catch-up growth by age 2 to 4 years and criteria 1 through 5 are met: 1. Documentation that patient was born SGA, defined as a birth weight and/or length of 2 or more standard deviations below the mean for gestational age and gender (including infants born with intrauterine growth restriction or Russell-Silver Syndrome resulting in SGA); 2. Documented short stature/growth failure (subnormal growth rate) by 2 years of age when height is 2 or more standard deviations below the mean for the patient's age and gender; 3. Documentation that other causes for short stature such as growth inhibiting medication, endocrine disorders, and emotional deprivation or syndromes have been ruled out; 4. Must provide an initial bone age and demonstration of open growth plates; 5. Minimum age requirement: 2 years old". - "E. Short stature or growth failure in children with short stature homeobox-containing gene (SHOX) deficiency and criteria 1 and 2 are met: 1. Must provide an initial bone age and demonstration of open growth plates; 2. Documented short stature/growth failure (subnormal growth rate) when height is at least 2 standard deviations below the normal mean for the patient's age and gender". 4. **Changed the following under Prior Authorization Criteria:** - "I. Documented diagnosis of one of the following conditions A through E…" **to** "I. Documented diagnosis of one of the following conditions A through G…" - "A1.…by meeting ONE of criteria a, b, c, d, OR e…" **to** "A1….by meeting ONE of criteria a through e…". - "A1b….for bone age and sex…" **to** "A1b.…for the patient's bone age and gender". - "A3a…. the age/sex" **to** "A3a….the patient's age and gender". - "A3b. Height is below the minimum percentile for the age/sex, and untreated growth velocity with a minimum of 1 year growth data is below the 25th percentile" **to** "A3b. Height is below the 5th percentile for the patient's age and gender, and untreated growth velocity with a minimum of 1 year of growth data is below the 25th percentile for the patient's age and gender". - "B. Prader-Willi Syndrome (PWS) and criteria 1 through 2 are met: 1. Documented biochemical growth hormone deficiency (GHD) by meeting ONE of criteria a, b, c, d, OR e: a. Two growth hormone (GH) stimulation tests below 10 ng/ml (microgram/L); b. At least one GH stimulation test level less than 15 ng/ml, AND IGF-l and IGF-BP3 levels below normal for bone age and sex; c. One GH stimulation test below 10 ng/ml (microgram/L) is sufficient for children with defined CNS pathology, history of irradiation or genetic conditions associated with GHD; d. GH stimulation tests, IGF-1 or IGF-BP3 levels are not needed for GHD if multiple pituitary hormone deficiencies exist (at least two other in addition to GHD); e.

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	GH stimulation tests, IGF-1 or IGF-BP3 levels are not needed for congenital GHD (low GH levels detected during acute episode of hypoglycemia)…" **to** "B. Growth failure due to Prader-Willi Syndrome (PWS) and criteria 1 and 2 are met: 1. Documentation that the diagnosis of PWS has been confirmed by appropriate genetic testing…". - "D. Turner's or Noonan's Syndrome and criteria 1 through 2 are met…2…. for age/sex" **to** "D. Growth failure associated with Turner's or Noonan's Syndrome and criteria 1 and 2 are met…2…. for the patient's age and gender". - "F. Chronic renal insufficiency (CRI)…2…. age/sex, … age/sex" **to** "F. Growth failure associated with Chronic renal insufficiency (CRI)…2....the patient's age and gender, … the patient's age and gender". 5. **Updated** "http://pi.lilly.com/us/humatrope-cart-pi.pdf" **to** "http://uspl.lilly.com/humatrope/humatrope.html#pi" **under References**. 6. **Added** "https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/growth-hormone-replacement-therapy-pmng"**,** "https://www.connecticare.com/provider/PDFs/Pharmacy/Growth%20Hormone%20New.pdf"**, and** "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** ";" to "." **and deleted** "OR"s at the end of each criteria line for "Documented biochemical growth hormone deficiency by meeting ONE of criteria a, b, c, d, OR e" below "Growth hormone deficiency (GHD)" and "Prader-Willi Syndrome (PWS)" criteria **under Prior Authorization Criteria.** 2. **Changed** "Short stature/growth failure (subnormal growth rate)" **to** "Documented short stature/growth failure (subnormal growth rate)" below "Growth hormone deficiency (GHD)" and "Turner's or Noonan's Syndrome" criteria **under Prior Authorization Criteria**. 3. **Changed** "Height is below the 5th percentile for the age/sex, and untreated growth velocity is below 25th percentile for age/sex" **to** "Height is below the minimum percentile for the age/sex, and untreated growth velocity with a minimum of 1 year growth data is below the 25th percentile" for "Documented short stature/growth failure (subnormal growth rate)" criteria below "Growth hormone deficiency (GHD)" criteria **under Prior Authorization Criteria**. 4. **Changed** "2. Short stature/growth failure (subnormal growth rate) when height is below the 5th percentile for age/sex, and untreated growth velocity is below 25th percentile for age/sex; 3. Patient requires weekly dialysis or has chronic renal insufficiency defined as glomerular filtration rate (GFR) < 75 ml/min / 1.73 m2" **to** "2. Documented short stature/growth failure (subnormal growth rate) when height is below the 5th percentile for age/sex, and untreated growth velocity with a minimum of 1 year of growth data is below the 25th percentile for age/sex; 3. Patient requires weekly dialysis or has a glomerular filtration rate (GFR) < 75 ml/min / 1.73 m2" below "Chronic renal insufficiency (CRI)" criteria **under Prior Authorization Criteria**. 5. **Changed** "Prescriber is an endocrinologist, pediatric nephrologist or trauma/burn surgeon" **to** "Prescriber is a pediatric endocrinologist, pediatric nephrologist, or trauma/burn surgeon" **under Prior Authorization Criteria**.

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	6. **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**. 7. **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**. 8. **Changed** "Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment" **to** "Children with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment" **under Exclusion Criteria**. 9. **Changed** "Pediatric burn: Up to 12 months. No further authorization shall be given" **to** "Pediatric burn: One time for up to 12 months" **under Authorization under Approval Length**. 10. **Changed** "Pediatric burn: No further authorization shall be given" **to** "Pediatric burn: N/A" **under Re-Authorization under Approval Length**. 11. **Changed** "All other diagnoses: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective by meeting criteria a through b: a. Growth velocity needs to be greater than 2.5 cm/year; b. Bone age must be obtained annually when chronological age reaches 13 in females or 15 in males. Therapy must not exceed bone age of 16 in males or 14 in females" **to** "All other diagnoses: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the patient's growth velocity is greater than 2.5 cm/year. Must also include documentation of a through b below, if applicable: a. Bone age must be obtained annually when chronological age reaches 15 in males or 13 in females. Therapy must not exceed a bone age of 16 in males or 14 in females; b. If diagnosis is chronic renal insufficiency (CRI), patient must still require weekly dialysis or have a glomerular filtration rate (GFR) < 75 ml/min / 1.73 m2" **under Re-Authorization under Approval Length**. 12. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Growth_Hormone.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/GrowthHormone.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**.
1/30/2014	1. **Adapted policy to new format.** 2. **Changed Generic Name from** "Somatropin (Children 0-18 years old)" **to** "Somatropin (Children)". 3. **Changed Therapeutic Class or Brand Name from** "Growth Hormone (Children 0-18 years old)" **to** "Growth Hormone (Children)". 4. **Made the following changes under Applicable Drugs:** Moved "Norditropin" from Preferred to Non-preferred line; added "Nutropin AQ®, Serostim®, and Zorbtive®" to Non-preferred line. 5. **Added GPI Codes**. 6. **Changed Prior Authorization Criteria from**: "Documented diagnosis of one of the Covered Uses listed below AND must meet criteria listed under applicable diagnosis: *Panhypopituitarism OR Turner Syndrome: Approved for ages 0-18 years old, must have started before age 16 years old; *Small gestational age: Request must be made before age 3 years old; Child has normal GH blood levels (may have documented GH resistance); Must be under the care of or have extensive endocrinologist consultation; A copy of the prescription signed by the physician must be submitted with application; *All other covered diagnoses (Endogenous growth hormone secretion of

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	<10ng.ml after provocative stimulation OR Growth failure associated with documented chronic renal insufficiency up to the time of renal transplantation OR Long-term treatment of idiopathic short stature, also called non-growth hormone-deficient short stature, defined by height SDS (Standard Deviation) <2.25 (Humatrope) OR Treatment of short bowel syndrome in patients receiving specialized nutritional support): Approved for ages 0-18 years old, must have started before age 16 years old; Must have a height stature less than the 5th percentile on the PHYSICAL GROWTH NCHS PERCENTILES CHART for correct age and sex; Growth rate must be documented in centimeters for at least 6 months immediately before initiation of growth hormone treatment; Prescribed by endocrinologist or with endocrinology consultation; Patients diagnosed with Prader Willi must complete a sleep oximetry study. If the oximetry is abnormal, a full polysomnography study is required. GH is contraindicated in patients with sleep apnea - PA will not be granted to clients that have sleep apnea; Age requirement: 0-18 years old; Non-preferred products require a documented trial and failure of or contraindication to a preferred product (Norditropin® and Tev-Tropin®)" **to:** "I. Documented diagnosis of one of the following conditions A through E AND must meet criteria listed under applicable diagnosis: A. Growth hormone deficiency (GHD) and criteria 1 through 3 are met: 1. Documented biochemical growth hormone deficiency by meeting ONE of criteria a, b, c, d, OR e: a. Two growth hormone (GH) stimulation tests below 10 ng/ml (microgram/L); OR b. At least one GH stimulation test level less than 15 ng/ml, AND IGF-l and IGF-BP3 levels below normal for bone age and sex; OR c. One GH stimulation test below 10 ng/ml (microgram/L) is sufficient for children with defined CNS pathology, history of irradiation or genetic conditions associated with GHD; OR d. GH stimulation tests, IGF-1 or IGF-BP3 levels are not needed for GHD if multiple pituitary hormone deficiencies exist (at least two other in addition to GHD); OR e. GH stimulation tests, IGF-1 or IGF-BP3 levels are not needed for congenital GHD (low GH levels detected during acute episode of hypoglycemia); 2. Must provide an initial bone age and demonstration of open growth plates; 3. Short stature/growth failure (subnormal growth rate) by meeting ONE of criteria a, b, OR c: a. Height is below the 3rd percentile for the age/sex; b. Height is below the 5th percentile for the age/sex, and untreated growth velocity is below 25th percentile for age/sex; c. If GHD criteria under 1e are met, short stature/growth failure is not needed; B. Prader-Willi Syndrome (PWS) and criteria 1 through 2 are met: 1. Documented biochemical growth hormone deficiency (GHD) by meeting ONE of criteria a, b, c, d, OR e: a. Two growth hormone (GH) stimulation tests below 10 ng/ml (microgram/L); OR b. At least one GH stimulation test level less than 15 ng/ml, AND IGF-l and IGF-BP3 levels below normal for bone age and sex; OR c. One GH stimulation test below 10 ng/ml (microgram/L) is sufficient for children with defined CNS pathology, history of irradiation or genetic conditions associated with GHD; OR d. GH stimulation tests, IGF-1 or IGF-BP3 levels are not needed for GHD if multiple pituitary hormone deficiencies exist (at least two other in addition to GHD); OR e. GH stimulation tests, IGF-1 or IGF-BP3 levels are not needed for congenital GHD (low GH levels detected during acute episode of hypoglycemia); 2. Must provide an initial bone age and demonstration of open growth plates; C. Turner's or Noonan's Syndrome and criteria 1 through 2 are met: 1. Must provide an initial bone age and demonstration of open growth plates; 2. Short stature/growth failure (subnormal growth rate) when height is below the 10^{th} percentile for age/sex; D. Chronic renal insufficiency (CRI) and criteria 1 through 3 are met: 1. Must provide an initial bone age and demonstration of open growth plates; 2. Short stature/growth failure (subnormal growth rate) when height is below the 5^{th} percentile for age/sex, and untreated growth velocity is below 25^{th} percentile for age/sex; 3. Patient requires weekly dialysis or has chronic renal insufficiency defined as glomerular filtration rate (GFR) < 75 ml/min / 1.73 m2; E. Pediatric burn patients and criterion 1 is met: 1. Burns are over at least 40% of the total body surface area; II. Prescriber is an endocrinologist, pediatric nephrologist or trauma/burn surgeon; III. Non-preferred products require a documented trial and failure of or contraindication to the preferred product (Tev-Tropin®)".

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	7. **Changed Exclusion Criteria from** "Diagnosis of sleep apnea" **to** "Acute Critical Illness; Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment; Active Malignancy; Active Proliferative or Severe Non-Proliferative Diabetic Retinopathy; Children with closed epiphyses". 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** "1 year" **to** "Pediatric burn: Up to 12 months. No further authorization shall be given; All other diagnoses: Up to 12 months or until maximum bone age is met (up to 16 years of age for males or 14 years of age for females), whichever is shorter". 10. **Changed Re-Authorization under Approval Length from:** "Copy of the current prescription, patient's current weight (kilograms) and height (centimeters), and chart-documented growth in the past year. Treated growth rate must exceed untreated rate by 2 centimeters per year (this last sentence does not apply to patients being treated for small gestational age); NOTE: Maximum covered time period for small gestational age only is 2 years" **to:** "Pediatric burn: No further authorization shall be given; All other diagnoses: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective by meeting criteria a through b: a. Growth velocity needs to be greater than 2.5 cm/year; b. Bone age must be obtained annually when chronological age reaches 13 in females or 15 in males. Therapy must not exceed bone age of 16 in males or 14 in females". 11. **Updated references** to include Regence policy, Medi-Span, and package inserts.