Introduction

Growth hormone is produced by the pituitary gland. It aids cell reproduction and promotes physical growth. Growth hormone also is important in how the body converts food into energy. The level of growth hormone varies during the day and is influenced by sleep, diet, stress, and exercise. During childhood, most children produce enough of this hormone for natural growth and development. Lack of enough growth hormone during childhood can result in a number of conditions. In adults, certain medical conditions can result in too little growth hormone. This policy describes when growth hormone therapy may be considered medically necessary for children and adults.

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

Growth hormone* may be considered medically necessary in the treatment of children who meet ALL criteria for the conditions listed below:

- Growth deficiency, secondary to insufficient endogenous growth hormone production;
- Patients with a history of intrauterine growth restriction (small for gestational age (SGA));
- Chronic renal failure (without functioning kidney transplant);
- Gonadal Dysgenesis (Turner Syndrome);
- Noonan Syndrome;
- Infantile hypoglycemia associated with panhypopituitarism; and
- Prader-Willi Syndrome (PWS)

*Genotropin and Omnitrope are considered first line agents. Use of a second line agent must be preapproved. (See Second Line Agents section below.)

### Diagnoses

Growth failure in children who are small for gestational age (SGA), intrauterine growth retardation, the initial request may be approved when ALL of the following criteria are met:

- Birth weight, birth length, or both are more than 2 standard deviations below the mean normal values following the adjustment for age and gender
  **AND**
- For patients aged 10 years or older, bone age must be less than 18 years or epiphyseal confirm to be open
  **AND**
- Normal height range (height >10th percentile for current age) is not reached by two years of age.
  
  **Note:** No biochemical testing is required. Approve for 12 months of treatment.

Growth failure in children who are small for gestational age (SGA), intrauterine growth retardation, continued treatment may be approved when ALL of the following criteria are met:

- The patient must have grown 2.5 centimeters over the previous year with growth hormone therapy
  **AND**
### Medical Necessity

**Children**

- For patients aged 10 years or older, bone age must be less than 18 years or epiphyses are confirmed to be open

  **Note:** Approve for an additional 12 months of treatment.

**Chronic renal failure (without functioning kidney transplant), the initial request may be approved when at least ONE of the following criterion is met:**

- Undergoing dialysis two or more times per week

  **OR**

- Serum creatinine > 2.0 mg/dL.

  **Note:** No biochemical testing is required. Initial approval will be 12 months. For continued approval for another 12 months, confirmation that the member still meets the above coverage criteria must be received.

**Gonadal Dysgenesis (Turner Syndrome) or Noonan Syndrome, the initial treatment may be approved when ALL of the following criteria are met:**

- For patients aged 10 years or older, bone age must be less than 18 years or epiphyses are confirmed to be open

  **AND**

- Height < 25th percentile for age

  **Note:** No biochemical testing is required. Approve for 12 months of treatment.

**Gonadal Dysgenesis (Turner Syndrome) or Noonan Syndrome may be approved for continued treatment when ALL of the following criteria are met:**

- For patients aged 10 years or older, bone age must be less than 18 years or epiphyses are confirmed to be open

  **AND**

- Height is < 25th percentile for age

  **AND**

- Patient has grown at least 2.5 centimeters over the previous year with growth hormone therapy

  **Note:** Approve for an additional 12 months of treatment, or may approve until age 14 and annually thereafter, as long as the above criteria are met.

**Infantile hypoglycemia associated with panhypopituitarism may be approved when:**
<table>
<thead>
<tr>
<th>Subject</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Children                                    | • Demonstrated blood sugar is < 40 mg %  
AND  
• Serum growth hormone level is < 10 ng/ml on all samples obtained during a hypoglycemic episode OR during one appropriate stimulation study  
Note: Approve for 12 months of treatment. In emergent situations, treatment may be started before test results are available; approve for 1 month. |
| Prader-Willi Syndrome (PWS), the initial request may be approved when the following criteria are met: | • Patient has height velocity (<10th percentile for age/sex)  
AND  
• For patients aged 10 years or older, bone age must be less than 18 years or epiphyses are confirmed to be open.  
Note: No biochemical testing is required. Initial approval for 12 months of treatment. |
| Prader-Willi Syndrome (PWS) may be approved for continued treatment when the following criteria are met: | • Patient has grown at least 2.5 centimeters over the previous year with growth hormone  
AND  
• For patients aged 10 years or older, bone age must be less than 18 years or epiphyses are confirmed to be open.  
Note: Approve for an additional 12 months of treatment. |
| Initial evaluation of new patients with diagnosis of growth hormone deficiency | Treatment of growth deficiency in children (including panhypopituitarism), secondary to insufficient endogenous growth hormone production, may be approved when ALL of the following criteria are present:  
• Height velocity <25th percentile for bone age  
AND  
• For patients aged 10 years or older, bone age must be less than 18 years or epiphyses are confirmed to be open  
AND  
• Height is below the 3rd percentile on growth charts for patient age and >2.25 SD below the mean for the patient age  
  ○ Exceptions to this height requirement include known acute |
<table>
<thead>
<tr>
<th>Subject</th>
<th>Medical Necessity</th>
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</thead>
<tbody>
<tr>
<td><strong>Children</strong></td>
<td>onset GHD, such as after pituitary surgery or high dose radiation therapy. <strong>AND</strong> • CHRONIC disease has been ruled out (except renal failure), including liver failure, malnutrition, malabsorption and hypothyroidism (unless hyperthyroidism is being treated with the appropriate thyroid hormone treatment) <strong>AND</strong> • Serum growth hormone levels of &lt; 10 ng/mL on all samples obtained, utilizing <strong>TWO</strong> separate appropriate (L-dopa, clonidine, arginine, insulin-induced hypoglycemia) stimulation studies <strong>OR</strong> serum insulin-like growth factor (IGF-1) level less than the lower limit of normal for patient age. <strong>Note:</strong> Approve for 12 months of treatment.</td>
</tr>
<tr>
<td><strong>Subsequent evaluation/reauthorization for children with diagnosed growth hormone deficiency</strong></td>
<td><strong>Additional treatment may be authorized when the following criteria are met:</strong> • Height velocity while on growth hormone must be ≥ 2.5cm over the previous year <strong>AND</strong> • For patients aged 10 years or older, bone age must be less than 18 years or epiphyses are confirmed to be open (e.g., through wrist film evaluation). <strong>Note:</strong> Approve for an additional 12 months of treatment.</td>
</tr>
<tr>
<td><strong>Children with chronic renal failure, medical necessity for growth hormone no longer exists following functioning renal transplantation</strong></td>
<td><strong>Adolescents and Young Adults</strong> Adolescents and young adults with severe long-standing multiple pituitary hormone deficiencies (MPHD or panhypopituitarism), those with genetic defects, and those with severe organic GHD can be excluded from GH retesting.</td>
</tr>
<tr>
<td><strong>Adults</strong></td>
<td><strong>Conditions</strong> <strong>Growth hormone</strong> may be considered medically necessary in the treatment of adults who meet ALL criteria for the</td>
</tr>
<tr>
<td>Subject</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>-------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Adults                  | **conditions listed below:**  
                           | - AIDS wasting syndrome  
                           | **AND**  
                           | - Severe growth hormone deficiency  
                           | **AND**  
                           | - Short bowel syndrome  
                           |  
                           | *Genotropin and Omnitrope are considered first line agents. Use of a second line agent must be preapproved. (See Second Line Agents section below.)  
                           |  
| Absolute contraindications | **Growth hormone therapy is considered not medically necessary in patients for whom it is contraindicated:**  
                           | - Patients with acute third-degree burns; and  
                           | - In some patients with multiple trauma, acute critical or chronic illness, or cancer. (See manufacturers’ labeling for details.)  
                           |  
| Other non-medically necessary uses | **Growth hormone is considered not medically necessary in the treatment of idiopathic short stature without growth hormone deficiency**  
                           |  
| Adults with AIDS wasting syndrome | **Initial requests of treatment with the growth hormone Serostim® (somatropin) will be approved when ALL of the following criteria are met:**  
                           | - There is a diagnosis of AIDS wasting syndrome/cachexia  
                           | **AND**  
                           | - The patient is $\geq 18$ years of age  
                           | **AND**  
                           | - The patient is not currently receiving treatment with Serostim®  
                           | **AND**  
                           | - The patient’s weight loss is not resulting from underlying treatable conditions (e.g., depression, bacterium avium complex, chronic infectious diarrhea or malignancy with the exception of Kaposi’s sarcoma limited to skin or mucous membranes)  
                           | **AND**  
                           | - The patient has unintentionally lost $\geq 10\%$ of body weight or is 90\% or less than their ideal body weight. (See chart in the Appendix.)  
                           |  
|                           | **Note:** Approve for 6 weeks of initial treatment.  


<table>
<thead>
<tr>
<th>Subject</th>
<th>Medical Necessity</th>
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</thead>
</table>
| Adults  | Requests for continued treatment with the growth hormone Serostim® somatropin beyond the first 6 weeks (for a maximum of 12 weeks of treatment) will be approved when the following criterion is met:  
- Clinical benefit is present after the first 6 weeks of treatment (eg, stabilization of weight or weight gain).  
**Note:** Approve for an additional 6 weeks of treatment, for a total of 12 weeks. |
| Adult growth hormone deficiency | Growth hormone therapy, initial requests must meet the following criterion:  
- Adult growth deficiency must be confirmed by a negative response to a growth hormone stimulation test (eg, serum GH levels of <5ng/ml on stimulation testing with any of the following: arginine, clonidine, glucagon, insulin, or levodopa).  
**OR**  
- Growth hormone deficiency may be assumed without a stimulation test if patient has had the pituitary removed or destroyed, or has had panhypopituitarism since birth.  
**Note:** Approve for 12 months of initial treatment.  
Growth hormone therapy may be approved for continued treatment beyond the first 12 months when the following criterion is met:  
- Treatment with growth hormone must result in clinical benefit (improvement in bone density or cholesterol studies).  
**Note:** Approve for 12 months of continued treatment. |
| Adults with short bowel syndrome | Treatment may be approved when ALL of the following criteria are met:  
- There must be documented diagnosis of short bowel syndrome  
**AND**  
- The patient must have at least 50 cm residual bowel  
**AND**  
- The patient must be receiving specialized nutritional support.  
**Note:** Approve for 4 weeks of treatment.  
**Medical necessity of growth hormone treatment is limited to one four-week course of therapy for short bowel syndrome.** |
### Subject: Medical Necessity

#### Adults

This is a lifetime maximum, as there are currently no studies showing that additional benefit is conferred by further treatment beyond four weeks.

### Treatment | Investigational
--- | ---
**Growth hormone, for conditions not specifically addressed** | Due to the lack of scientific evidence concerning health outcomes, the use of growth hormone for conditions not specifically addressed in this policy is considered investigational, including, but not limited to the following conditions:
- Anabolic therapy, except for AIDS, provided to counteract acute or chronic catabolic illness (e.g., surgery outcomes, trauma, cancer, chronic hemodialysis) producing catabolic (protein wasting) changes in both adult and pediatric patients
- Anabolic therapy to enhance body mass or strength for professional, recreational, or social reasons
- Constitutional delay (lower than expected height percentiles when compared with target height percentiles and delayed skeletal maturation when growth velocities and rates of bone age advancement are within the normal range)
- Geriatric patient therapy
- Glucocorticoid-induced growth failure
- Non-GH-deficient short stature, except for Turner’s syndrome, Noonan syndrome and Prader-Willi Syndrome
- Post-polio syndrome
- Short stature after functional renal transplantation
- Short stature associated with Lupron therapy
- Short stature due to Down’s syndromes

**Note:** Mecasermin (Increlex™) is not a growth hormone product and is addressed separately in another medical policy (see Related Policies).
Second Line Agents

Second line agents may be considered medically necessary only under the following conditions:

- Norditropin: Noonan Syndrome
- Nutropin, Nutropin AQ: Chronic renal failure (without functioning kidney transplant)
- Zomacton, Saizen: Administration of growth hormone for medically necessary purposes AND is using a needleless injector AND member has documented needle-phobia
- Humatrope: Treatment of short stature or growth failure associated with SHOX deficiency
- Any non-preferred product if member either:
  - Has been previously stabilized on non-preferred therapy AND suffers cognitive deficiency of such severity that they cannot be trained to use a preferred product’s injection device AND were previously self-administering growth hormone independently
  - Has experienced a documented therapeutic failure on a preferred product

Other diagnosis will be considered on a case-by-case basis.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>HCPCS</td>
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<tr>
<td>J2941</td>
<td>Injection, somatropin, 1mg</td>
</tr>
<tr>
<td>S9558</td>
<td>Home injectable therapy; growth hormone, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information
Benefit Application

Individual enrollees receiving synthetic growth hormone should be reviewed on at least an annual basis to assure proper application of benefits.

Growth hormone may be covered under the drug or medical benefit, according to the member contract.

Most member contracts specifically exclude coverage of growth hormone for idiopathic short stature syndrome (ISS).

This policy is applicable to enrollees who are managed by the Company's Pharmacy Formulary. It does not apply to enrollees managed under the Express Scripts Formulary.

Evidence Review

Description

Synthetic growth hormone has been shown to increase growth rate and eventual adult height when given to children who are growth hormone-deficient. It has also been shown to increase strength, muscle mass, exercise capacity, and quality of life when given to growth hormone-deficient adults. Growth hormone is an anabolic and anti-catabolic agent which results in an increase in lean body mass (LBM), a decrease in body fat, and an overall significant increase in body weight due to the dominant effect of LBM gain.

The U.S. Food and Drug Administration (FDA) has approved this drug for the long-term treatment of growth failure in children due to:

1. Lack of adequate endogenous growth hormone secretion;
2. Chronic renal failure prior to transplantation;
3. Turner's Syndrome or Noonan Syndrome; and
4. Prader-Willi Syndrome

It is also indicated for the treatment of children with short stature born small for gestational age (SGA) with no catch-up growth by age two- to four-years; and idiopathic short stature (ISS), also
called non-growth hormone-deficient short stature. The FDA has also approved this drug for adult patients with somatotropin-deficiency or AIDS wasting syndrome.

Rationale

2008 Update

Several reviews of growth hormone (GH) therapy addressing specific issues were found.

In 2005, Deijen et al. reported a meta-analysis of studies of patient-reported outcomes (PRO) of growth hormone therapy in adults based on a search of PubMed and PiCarta between 1985 and 2004. Eligible studies reported quantitative data about the effect of GH therapy on PRO in GH deficient adults and were placebo-controlled or cross-over/parallel or open clinical trials with endpoints documented by validated questionnaires. Case reports, review articles and studies in which the psychometric quality of the used questionnaire was unknown were excluded, as were studies on GH therapy for other diseases (Turner’s syndrome, Prader-Willi Syndrome, fibromyalgia, etc.). Fifteen studies totaling 830 patients met the inclusion criteria. The authors divided PROs into three categories: quality of life (QOL), health status and wellbeing. Of the three, wellbeing endpoints had the largest effect size, the other two being small. The authors concluded that it is difficult to evaluate the psychological effects of GH in adults, but the QOL impact in this population may frequently be overrated.

A recent systematic review of GH studies in HIV-associated cachexia indexed in MEDLINE through August 2007 was conducted by Gelato et al. In evaluating articles for inclusion, preference was given to clinical studies (including randomized clinical studies), meta-analyses, and guidelines. Review articles that focused on HIV-associated wasting were evaluated and their reference lists examined for additional relevant publications. Statistically significant weight gains were reported, but the average increase was only three kg. Offsetting side effects included hyperglycemia, arthralgia, myalgia and peripheral edema. Subjective improvements in PRO were reported, but the overall value of GH therapy in this population remains to be determined.

A Cochrane review of GH treatment of idiopathic short stature syndrome (ISS) was published in 2007. These children are very short for their age, but have normal GH levels and no known cause of their shortness. Ten RCTs were found with final height as primary endpoint. These were meta-analyzed when appropriate, using a random effects model. Incremental increases in final height were modest (1.5-4 inches). One study reported health related QOL and showed no significant improvement in GH treated children compared with those in the control group, while another
found no significant evidence that GH treatment impacts psychological adaptation or self-perception in children with ISS.

**2009 Update**

The 2006 Endocrine Society guidelines for treatment of GH deficiency in adults were reviewed to update the policy guidelines for adults. Key recommendations of this panel include:

- Patients with childhood-onset growth hormone deficiency (GHD) who are appropriate candidates for GH) therapy should be retested for GHD as adults unless they have known mutations, embryopathic lesions, or irreversible structural lesions/damage (level of evidence, high).

- Adult patients with evidence of structural hypothalamic/pituitary disease, surgery or irradiation to these areas, or other pituitary hormone deficiencies should be considered for evaluation for acquired GHD (level of evidence, high).

- The insulin tolerance test (ITT) or the growth hormone releasing hormone (GHRH)-arginine test is the preferred test for establishing the diagnosis of GHD. However, in those with clearly established recent hypothalamic causes of suspected GHD (e.g., irradiation) testing with GHRH-arginine may be misleading (level of evidence, high).

- Because of the irreversible nature of the cause of the GHD in children with structural lesions with multiple hormone deficiencies and those with proven genetic causes, a low insulin-like growth factor I (IGF-I) level at least one month off GH therapy is sufficient documentation of persistent GHD without additional provocative testing (level of evidence, moderate).

The criteria for initiation and continuation of GH in children were revised by comparison with the Lawson Wilkins Society pediatric GH guidelines as updated in 2003. Normal Height velocities for normal boys and girls were obtained from the growth charts available at [www.cdc.gov](http://www.cdc.gov).

**2010 Update**

A literature search of the MEDLINE database did not identify any additional published studies that would prompt reconsideration of the policy statements, which remain unchanged.
2011 Update

A literature search of the MEDLINE database did not identify any additional published studies that would substantively change the policy statements. Policy reformatted and revised for administrative simplification.

2012 Update

A literature search of the MEDLINE database did not identify any additional published studies that would prompt reconsideration of the policy statements, which remain unchanged. The 2009 update on the AACE guidelines for growth hormone use for growth hormone-deficient adults was added to the reference section.

2013 Update

Literature search of PUBMED database did not identify any additional published studies that would prompt policy change. Added that stimulation test is not necessary in adults who are known to not have a functioning pituitary.

2014 Update

Literature search of PUBMED database did not identify any additional published studies that would prompt medical change. Added that growth hormone may be approved up to age 14 and annually thereafter in patients with Turner or Noonan syndromes.

References


### Height and Weight Table for Men*

<table>
<thead>
<tr>
<th>Height (feet/inches)</th>
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<th>Large Frame</th>
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<td>171 – 187</td>
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</table>

Weights at ages 25-59 based on lowest mortality. Weight in pounds according to frame (in indoor clothing weighing 5 lbs.; shoes with 1" heels).

### Height and Weight Table for Women*

<table>
<thead>
<tr>
<th>Height (feet/inches)</th>
<th>Small Frame</th>
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Weights at ages 25-59 based on lowest mortality. Weight in pounds according to frame (in indoor clothing weighing 3 lbs.; shoes with 1" heels).


History

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<td>06/01/99</td>
<td>Replace Policy - Changed criteria for adults</td>
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<td>Replace Policy - Policy reformatted; no criteria changes.</td>
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<td>03/15/02</td>
<td>Replace Policy - Policy updated to reflect current consensus guidelines.</td>
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<td>05/11/04</td>
<td>Replace Policy - Policy reviewed and updated, with policy statement and guidelines updated for clarification purposes. Now considered medically necessary for intrauterine growth restriction/ SGA. Crohn's Disease and cystic fibrosis added list of investigational uses.</td>
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<td>Replace Policy - Policy statement changed; Idiopathic short stature changed from investigational to not medically necessary.</td>
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<td>Replace Policy - Policy updated with literature search. Reviewed and approved by P&amp;T on March 22, 2005; policy statement is changed to include adults with short bowel syndrome as medically necessary.</td>
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<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
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<tr>
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<td>Replace Policy - Policy updated with literature search; baseline study requirements removed from criteria for adult patient growth hormone therapy; policy statement unchanged; Scope and Disclaimer updated.</td>
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<tr>
<td>07/25/06</td>
<td>Replace Policy - Policy reviewed by the Pharmacy and Therapeutic Committee; recommended without changes.</td>
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</tr>
<tr>
<td>03/13/07</td>
<td>Replace Policy - Clarification added under Policy Guidelines indicating the continuation of treatment for pituitary dwarfism without additional testing. No other changes.</td>
</tr>
<tr>
<td>03/21/07</td>
<td>Codes Updated - No other changes.</td>
</tr>
<tr>
<td>05/08/07</td>
<td>Replace Policy - Policy updated with a statement added to the Policy section indicating that medical necessity determination is not required for Mecasermin (Iplex Incrilex).</td>
</tr>
<tr>
<td>10/9/07</td>
<td>Replace Policy - Policy updated with a statement added to the Policy section indicating that a benefit advisory is not required for Mecasermin replacing &quot;Medical necessity determination is not a requirement for this indication&quot;. Under Policy guidelines &quot;No biochemical testing is required&quot; was added and section title was clarified.</td>
</tr>
<tr>
<td>08/12/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. A note was included at the end of the policy statement referencing the Mecasermin policy. Policy reviewed by the Pharmacy and Therapeutic Committee; recommended no changes. Rationale updated and references added.</td>
</tr>
<tr>
<td>10/14/08</td>
<td>Code Update - J9225 and J9226 removed, no other changes.</td>
</tr>
<tr>
<td>11/11/08</td>
<td>Code Update - J1675 removed, no other changes.</td>
</tr>
<tr>
<td>07/29/09</td>
<td>Update Benefit Application - No other changes.</td>
</tr>
<tr>
<td>08/11/09</td>
<td>Replace Policy - Policy updated with literature search. Policy statement updated to include Medically necessary indication (2 bullets) under the “Children” section. P&amp;T reviewed on July 28, 2009.</td>
</tr>
<tr>
<td>12/14/10</td>
<td>Replace Policy - Policy updated with literature review; no change in policy statements. Reviewed by P&amp;T November 2010.</td>
</tr>
<tr>
<td>03/08/11</td>
<td>Replace Policy - Policy updated with literature review; no change in policy statements. Policy re-written and reformatted for improved clarity and administrative simplification.</td>
</tr>
<tr>
<td>09/11/12</td>
<td>Replace policy. Policy updated with literature review through July 2012. Reference #45</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>10/15/12</td>
<td>Replace policy. Policy guidelines revised with addition of clarifying statement “For patients aged 10 years or older, bone age must be less than 18 years or epiphyses are confirmed to be open”. Policy statement unchanged. Medco replaced with Express Scripts within Benefit Application.</td>
</tr>
<tr>
<td>11/13/12</td>
<td>Replace policy. Genotropin and Omnitrope added as first line agents as referenced in the existing medically necessary policy statement. Second line agents have been addressed in the Policy Guidelines, with outlining conditions for which they may be approved.</td>
</tr>
<tr>
<td>10/14/13</td>
<td>Replace policy. Policy Guidelines section updated with the addition that stimulation test is not necessary in adults who are known to not have a functioning pituitary.</td>
</tr>
<tr>
<td>12/03/13</td>
<td>Coding Updating. Add ICD-10 codes.</td>
</tr>
<tr>
<td>11/10/14</td>
<td>Annual review. Policy updated with literature review; no change to policy statement. Added that growth hormone may be approved up to age 14 and annually thereafter in patients with Turner or Noonan syndromes within the Policy Guidelines section.</td>
</tr>
<tr>
<td>06/09/15</td>
<td>Interim update. Replace name of Tev-Tropin with Zomacton – name change by manufacturer.</td>
</tr>
<tr>
<td>04/01/16</td>
<td>Coding Update. Removed HCPCS J2940.</td>
</tr>
<tr>
<td>10/01/16</td>
<td>Annual Review, approved September 13, 2016. Update of the re-authorization criteria for adult GH use.</td>
</tr>
<tr>
<td>10/21/16</td>
<td>Minor edit. Removed an example of clinical benefit in Adult Growth Hormone Deficiency section.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentinquines@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

If you also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/office/file/index.html, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You may need to take action by certain deadlines to keep your health coverage or help with costs. You may need to take action by certain deadlines to keep your health coverage or help with costs. You may need to take action by certain deadlines to keep your health coverage or help with costs.

Call 800-722-1471 (TTY: 800-842-5357).

中文 (Chinese):
本通知有重要訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保費的重要訊息。本通知可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

Italiano (Italian):
Román (Romanian):

Polskie (Polish):
To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie praw Pyłania prezentyw wobec Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utraty polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie prawo do bezpłatnej informacji we własnym języku. Zadzwonite pod 800-722-1471 (TTY: 800-842-5357).

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir dados importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde e ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

ไทย (Thai):
ประกาศนี้มีข้อมูลสําคัญ ประกาศนี้มีข้อมูลสําคัญเกี่ยวกับการขอความช่วยเหลือของประกันสุขภาพของคุณกับ Premera Blue Cross และทุกอย่างที่เกี่ยวข้องในกรณีที่คุณควรจะ ดําเนินการในกําหนดเวลาที่แน่นอนเพื่อดําเนินการประกันสุขภาพของคุณช่วงชีวิตที่ มีการให้ข้อมูลที่มีคุณภาพและข้อมูลที่เกี่ยวข้องในการระดับที่มีความคิดชัดเจน โทร 800-722-1471 (TTY: 800-842-5357).