

# Growth Hormones

## **Goal(s):**

- Restrict use of growth hormone (GH) in adults for where there is medical evidence of effectiveness and safety and supported by expert guidelines.

NOTE: Treatment with GH in children and adolescents (for any indication) are evaluated for medical appropriateness and medical necessity on a case-by-case basis.

## **Length of Authorization:**

- Up to 12 months

## **Requires PA:**

- All GH products require prior authorization for OHP coverage. Treatment is not included for use in antiaging therapy or to enhance athletic ability or for body building.

## **Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at [www.orpdl.org](http://www.orpdl.org)
- Searchable site for Oregon FFS Drug Class listed at [www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

**Table 1. Pediatric and Adults FDA Approved Indications for Growth Hormone**

somatropin										Lonapeg-somatropin
	Genotropin	Norditropin	Nutropin AQ	Humatrope	Omnitrope	Saizen	Serostim	Zorbtive	Zomacton	Skytrofa
<b>Pediatric Indications</b>										
GHD	X	X	X	X	X	X			X	X
Prader-Willi Syndrome	X	X			X					
Noonan Syndrome		X								
Turner Syndrome	X	X	X	X	X				X	
Idiopathic Short Stature	X	X	X	X	X				X	
SHOX Deficiency				X					X	
Growth Failure Secondary to CKD			X							
Small for Gestational Age	X	X		X	X				X	
HIV Associated Cachexia							X			
<b>Adult Indications</b>										
GHD	X	X	X	X	X	X			X	
HIV Associated Cachexia							X			
SBS								X		

Abbreviations: CKD = chronic kidney disease; FDA = Food and Drug Administration; GHD = growth hormone deficiency; HIV = human immunodeficiency virus; SBS = short bowel syndrome; SHOX = Short stature homeobox-containing gene

<b>Approval Criteria</b>		
1. What is the diagnosis being treated?	Record ICD10 code	
2. Is the diagnosis promotion of growth delay in a child with 3 <sup>rd</sup> degree burns?	<b>Yes:</b> Document and send to DHS Medical Director for review and pending approval	<b>No:</b> Go to #3
3. Is the request for one of the conditions listed below? For children and adolescents age 17 and younger <ul style="list-style-type: none"> <li>• Growth hormone deficiency (GHD)</li> <li>• Prader-Willi syndrome</li> <li>• Noonan syndrome</li> <li>• Turner syndrome</li> <li>• Idiopathic Short Stature</li> <li>• Growth Failure secondary to chronic kidney disease (CKD)</li> <li>• Small for gestational age</li> <li>• Short stature homeobox-containing (SHOX) gene deficiency</li> <li>• HIV Associated Cachexia</li> </ul> For adults age 18 years and older <ul style="list-style-type: none"> <li>• Growth hormone deficiency (GHD)</li> <li>• HIV Associated Cachexia</li> <li>• Short Bowel Syndrome (SBS)</li> </ul>	<b>Yes:</b> Go to #4	<b>No:</b> For current age ≥ 21 years: Pass to RPh. Deny; medical appropriateness  For current age < 21 years: Go to #5.
4. Has the provider documented goals of therapy and objective baseline assessment (e.g., quality of life, exercise capacity, height, body composition improvements, etc)? Note: these same assessments should be evaluated for continuation of treatment.	<b>Yes:</b> Go to #6	<b>No:</b> Pass to RPh. Deny; medical appropriateness
5. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?	<b>Yes:</b> Go to #11	<b>No:</b> Pass to RPh. Deny; medical appropriateness
6. Is this a request for initiation of growth hormone therapy?	<b>Yes:</b> Go to #7	<b>No:</b> Go to <b>Renewal Criteria</b>

## Approval Criteria

<p>7. Is the agent being prescribed by, or in consultation with, an appropriate specialist (e.g., an endocrinologist for adults or a pediatric endocrinologist or pediatric nephrologist for children/adolescents)?</p>	<p><b>Yes:</b> Go to #8</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness</p>
<p>8. Is the request for a pediatric patient with Prader-Willi syndrome who also has:</p> <ul style="list-style-type: none"> <li>• Severe obesity? Or</li> <li>• A history of upper airway obstruction or sleep apnea? Or</li> <li>• Severe respiratory impairment?</li> </ul> <p>Note: Recombinant somatropin is contraindicated in these patients due to the risk of sudden death.</p>	<p><b>Yes:</b> Pass to RPh. Deny; medical appropriateness</p>	<p><b>No:</b> Go to #9</p>
<p>9. Is the request for treatment of hypopituitarism (E23.0)?</p>	<p><b>Yes:</b> Go to #10</p>	<p><b>No:</b> Go to #11</p>
<p>10. Is the growth hormone deficiency confirmed by a negative response to a growth hormone stimulation test (eg, serum GH levels of &lt;5 ng/ml on stimulation testing with either glucagon or insulin)? <u>OR</u> Is there evidence that the patient had the pituitary removed/destroyed or has had panhypopituitarism since birth?</p>	<p><b>Yes:</b> Go to #11</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness</p>
<p>11. Is the request for a preferred product OR has the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 preferred products? Message: Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy &amp; Therapeutics Committee.</p>	<p><b>Yes:</b> Approve for up to 12 months</p>	<p><b>No:</b> Go to #12</p>
<p>12. Will the prescriber change to a preferred product? <u>Message:</u></p> <ul style="list-style-type: none"> <li>• Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&amp;T) Committee.</li> </ul>	<p><b>Yes:</b> Inform prescriber of covered alternatives in class and approve for up to 12 months.</p>	<p><b>No:</b> Go to #13</p>

## Approval Criteria

13. Is the request for lonapegsomatropin?	<b>Yes:</b> Go to #14	<b>No:</b> Approve for up to 6 months
14. Is the request for a pediatric patient 1 year or older with a body weight $\geq 11.5$ kg?	<b>Yes:</b> Approve for up to 6 months	<b>No:</b> Pass to RPh. Deny; medical appropriateness.

## Renewal Criteria

1. Document approximate date of initiation of therapy and diagnosis (if not already done).		
2. Was treatment with this agent initiated in a patient prior to reaching adulthood (<18 years of age) to improve growth velocity or height?	<b>Yes:</b> Go to #3	<b>No:</b> Go to #5
3. Is growth velocity 2 cm or more per year?	<b>Yes:</b> Go to #6	<b>No:</b> Go to #4
4. Is there documentation that benefits of therapy continue to outweigh risks?  When main goal of therapy is growth promotion in children to normalize final adult height, current guidelines recommend discontinuation of treatment once growth velocity is less than 2-2.5 cm per year. Risks, benefits, and goals of therapy should be reassessed in patients whose epiphyses are closed.	<b>Yes:</b> Go to #5	<b>No:</b> Pass to RPh. Deny; medical appropriateness.
5. Is there documentation of improvement from baseline as assessed by the prescribing provider?	<b>Yes:</b> Go to #6	<b>No:</b> Pass to RPh. Deny; medical appropriateness.
6. Is the product requested preferred?	<b>Yes:</b> Approve for up to 12 months	<b>No:</b> Go to #7
7. Will the prescriber consider a change to a preferred product?  <u>Message:</u> <ul style="list-style-type: none"> <li>Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&amp;T) Committee.</li> </ul>	<b>Yes:</b> Inform prescriber of covered alternatives in class and approve for up to 12 months	<b>No:</b> Approve for up to 6 months

P&T Review: 4/23 (DE); 12/22;12/21; 6/21;11/18; 9/17; 9/16; 9/15; 9/14; 9/10; 5/10; 9/08; 2/06; 11/03; 9/03  
 Implementation: 1/1/19; 10/13/16; 1/1/11, 7/1/10, 4/15/09, 10/1/03, 9/1/06; 10/1/03