

## Growth Hormones

### **Goal(s):**

- Restrict use of growth hormone (GH) for funded diagnoses where there is medical evidence of effectiveness and safety.

NOTE: Treatment with GH in children should continue only until adult height, as determined by bone age, is achieved. Treatment is not included for isolated deficiency of human growth hormone in adults.

### **Length of Authorization:**

- Up to 12 months

### **Requires PA:**

- All GH products require prior authorization for OHP coverage. Treatment of human growth hormone deficiency for adults is not funded by the OHP.

### **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/)

<b>Initial Approval Criteria</b>		
1. What is the diagnosis being treated?	Record ICD10 code	
2. Is the request for an FDA approved indication?	<b>Yes:</b> Go to #3	<b>No:</b> Pass to RPh. Deny; medical appropriateness
3. Is this a request for initiation of growth hormone?	<b>Yes:</b> Go to #4	<b>No:</b> Go to <b>Renewal Criteria</b>
4. Is the agent being prescribed by, or in consultation with, a pediatric endocrinologist or pediatric nephrologist?	<b>Yes:</b> Go to #5	<b>No:</b> Pass to RPh. Deny; medical appropriateness
5. Is the patient an adult (>18 years of age)?	<b>Yes:</b> Go to #10	<b>No:</b> Go to #6
6. Is the diagnosis funded?	<b>Yes:</b> Go to #7	<b>No:</b> Pass to RPh. Deny; medical appropriateness
7. Is the diagnosis promotion of growth delay in a child with 3rd degree burns?	<b>Yes:</b> Document and send to DHS Medical Director for review and pending approval	<b>No:</b> Go to #8

## Initial Approval Criteria

<p>8. If male, is bone age &lt;16 years? If female, is bone age &lt;14 years?</p>	<p><b>Yes:</b> Go to #9</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness</p>
<p>9. Is there evidence of non-closure of epiphyseal plate?</p>	<p><b>Yes:</b> Go to #11</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness</p>
<p>10. Is the request for the treatment of isolated human growth hormone deficiency in an adult (E23.0) or short stature due to an endocrine disorder (E34.3), or another unfunded condition?</p> <p>Per Guideline Note 74, treatment with GH for children with conditions such as panhypopituitarism, iatrogenic and other pituitary disorders, as well as gonadal dysfunction, should only continue until adult height, as determined by bone age, is achieved.</p>	<p><b>Yes:</b> Pass to RPh. Deny; not funded by the OHP.</p>	<p><b>No:</b> Go to #11</p>
<p>11. Is the request for a pediatric patient with Prader-Willi syndrome who 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 # 12</p>
<p>12. Is the requested product preferred?</p>	<p><b>Yes:</b> Approve for up to 12 months</p>	<p><b>No:</b> Go to #13</p>
<p>13. Will the prescriber consider a change to a preferred product that is FDA-approved for the condition?</p> <p><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 #14</p>

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14. Is the request for lonapegsomatropin?	<b>Yes:</b> Go to #15	<b>No:</b> Approve for up to 12 months
15. Is the request for a pediatric patient 1 year or older with a body weight >11.5 kg?	<b>Yes:</b> Approve for up to 12 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 patient prior to reaching adulthood (<18 years of age)?	<b>Yes:</b> Go to #3	<b>No:</b> Go to #5
3. Is growth velocity greater than 2.5 cm per year?	<b>Yes:</b> Go to #4	<b>No:</b> Pass to RPh. Deny; medical appropriateness
4. Is male bone age <16 years or female bone age <14 years?	<b>Yes:</b> Go to #6	<b>No:</b> Pass to RPh. Deny; medical appropriateness
5. Is the request for isolated human growth hormone deficiency in an adult (E23.0), short stature due to an endocrine disorder (E34.3), or another unfunded condition?	<b>Yes:</b> Pass to RPh. Deny; not funded by the OHP.	<b>No:</b> Go to #6
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 12 months

P&T Review: 12/21 (DE); 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: 1/1/22; 1/1/19; 10/13/16; 1/1/11, 7/1/10, 4/15/09, 10/1/03, 9/1/06; 10/1/03