

## Vosoritide

### Goal(s):

- Ensure medically appropriate use of approved agents for the treatment of achondroplasia in pediatric patients

### Length of Authorization:

- Up to 12 months

### Requires PA:

- Vosoritide

### 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:**

Actual Body Weight*	Dose	Injection Volume	Vial Strength for Reconstitution**
3 kg	0.096 mg	0.12 mL	0.4 mg
4 kg	0.12 mg	0.15 mL	0.4 mg
5 kg	0.16 mg	0.2 mL	0.4 mg
6 to 7 kg	0.2 mg	0.25 mL	0.4 mg
8 to 11 kg	0.24 mg	0.3 mL	0.4 mg
10-11 kg	0.24 mg	0.3 mL	0.4 mg
12-16 kg	0.28 mg	0.35 mL	0.56 mg
17-21 kg	0.32 mg	0.4 mL	0.56 mg
22-32 kg	0.4 mg	0.5 mL	0.56 mg
33-43 kg	0.5 mg	0.25 mL	1.2 mg
44-59 kg	0.6 mg	0.3 mL	1.2 mg
60-89 kg	0.7 mg	0.35 mL	1.2 mg
≥90 kg	0.8 mg	0.4 mL	1.2 mg

\*=Intermediate body weights that fall within these weight bands should be rounded to the nearest whole number.

\*\*=The concentration of vosoritide in reconstituted 0.4 mg vial and 0.56 mg vial is 0.8 mg/mL. The concentration of vosoritide in reconstituted 1.2 mg vial is 2 mg/mL.

## Approval Criteria

1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this an FDA approved indication based on diagnosis and current age restrictions?	<b>Yes:</b> Go to #3	<b>No:</b> Pass to RPh. Deny; medical appropriateness
3. Is the prescribed agent being dosed according to actual body weight (ABW) as outlined in Table 1?	<b>Yes:</b> Go to #4	<b>No:</b> Pass to RPh. Deny; medical appropriateness
4. Is the request for continuation of therapy in a patient previously approved by FFS?	<b>Yes:</b> Go to Renewal Criteria	<b>No:</b> Go to #5
5. Is the agent prescribed by, or in consultation with, a pediatric endocrinologist, neurologist, or other prescriber specialized in the care of patients with achondroplasia or skeletal dysplasia?	<b>Yes:</b> Go to #6	<b>No:</b> Pass to RPh. Deny; medical appropriateness
6. Is there documented evidence of a baseline measurement of annualized growth velocity (AGV) within the last 90 days AND, if male $\geq 15$ years or female $\geq 13$ years old, evidence of non-closure of epiphyseal plates?	<b>Yes:</b> Go to #7	<b>No:</b> Pass to RPh. Deny; medical appropriateness
7. Does the patient have a history of bone-related surgery or fracture of long bone or spine within the previous 6 months or planned bone surgery?	<b>Yes:</b> Pass to RPh. Deny; medical appropriateness	<b>No:</b> Go to #8
8. Does the patient have a diagnosis of recurrent symptomatic hypotension with or without orthostasis?	<b>Yes:</b> Pass to RPh. Deny; medical appropriateness	<b>No:</b> Approve for 6 months

## Renewal Criteria

1. Is this an FDA approved indication based on diagnosis and current age restrictions?	<b>Yes:</b> Go to #2	<b>No:</b> Pass to RPh. Deny; medical appropriateness
2. Is there documented evidence that the regimen is well tolerated with no adverse effects or drug toxicity?	<b>Yes:</b> Go to #3	<b>No:</b> Pass to RPh. Deny; medical appropriateness

## Renewal Criteria

<p>3. Is there documented evidence of adherence of at least 85% to the approved therapy regimen verified through claims history and/or provider assessment</p> <p>OR</p> <p>If adherence less than 85% of the time, there is documentation that the discontinuation was temporary due to the need for surgery or treatment of an infection?</p>	<p><b>Yes:</b> Go to #4</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness</p>
<p>4. Is this the first renewal request?</p>	<p><b>Yes:</b> Approve for 6 months</p>	<p><b>No:</b> Go to #5</p>
<p>5. Is there documented evidence of an improvement in annualized growth velocity (AGV) <math>\geq 1.0</math> cm/year from baseline AND, if male <math>\geq 15</math> years or female <math>\geq 13</math> years old, evidence of non-closure of epiphyseal plates?</p>	<p><b>Yes:</b> Approve for 12 months</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness</p>

P&T/DUR Review: 4/22 (DE)  
Implementation: 5/1/22