

C-type Natriuretic Peptides

Goal:

- 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 and navepegritide (pharmacy claims)

Covered Alternatives:

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

Table 1: Vosoritide Weight-Based Dosing

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
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.

Table 2. Navepegritide Weight-Based Dosing

Patient Body Weight	Weekly Dose	Injection Volume	Vial Strength for Reconstitution*
8 to 9.9 kg	0.88 mg	0.4 mL	1.3 mg
10 to 13.4 kg	1.2 mg	0.55 mL	
13.5 to 17.5 kg	1.6 mg	0.35 mL	2.8 mg

17.6 to 23 kg	2.1 mg	0.45 mL	5.5 mg
23.1 to 30.5 kg	2.8 mg	0.6 mL	
30.6 to 41.2 kg	3.6 mg	0.65 mL	
41.3 to 55.9 kg	5 mg	0.9 mL	
56 to 73.5 kg	6.6 mg	1.2 mL (use 2 kits; administer 0.6 mL from each kit)	
73.6 to 90 kg	8.8 mg	1.6 mL (use 2 kits; administer 0.8 mL from each kit)	

*The concentration of navepegritide is 2.2 mg/mL in a reconstituted 1.3 mg vial; 4.6 mg/mL in a 2.8 mg vial; and 5.5 mg/mL in a 5.5 mg vial

Approval Criteria		
1. What diagnosis is being treated?	Record ICD-10 code.	
2. Is this an FDA-approved indication based on diagnosis and current age restrictions? *Vosoritide is approved for all pediatric patients and navepegritide is approved for pediatric patients aged 2 years and older	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is the prescribed agent being dosed according to actual body weight (ABW) as outlined in Tables 1 and 2?	Yes: Go to #4	No: Pass to RPh. Deny; medical appropriateness
4. Is the request for continuation of therapy in a patient previously approved under fee-for-service (FFS) criteria?	Yes: Go to Renewal Criteria	No: 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?	Yes: Go to #6	No: 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 (for males ≥ 15 years or females ≥ 13 years old) documented non-closure of epiphyseal plates?	Yes: Go to #7	No: 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?	Yes: Pass to RPh. Deny; medical appropriateness	No: Approve for 6 months

Renewal Criteria		
1. Is this FDA-approved for the diagnosis and current age restrictions?	Yes: Go to #2	No: Pass to RPh. Deny; medical appropriateness
2. Is there documented evidence of $\geq 85\%$ adherence to therapy regimen (verified through claims history and/or provider assessment) OR $< 85\%$ adherence with documented temporary interruption due to surgery or infection?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is this the first renewal request?	Yes: Approve for 6 months	No: Go to #4
4. Is there documented evidence of an improvement in annualized growth velocity (AGV) ≥ 1.0 cm/year from baseline AND, if male ≥ 15 years or female ≥ 13 years old, evidence of non-closure of epiphyseal plates?	Yes: Approve for 12 months	No: Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 8/26 (DM); 4/22 (DE)
Implementation: 10/1/26; 5/1/22