CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	VOXZOGO (vosoritide)
BILLING CODE	68135-082-36/68135-119-66/68135-181-93
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

VOXZOGO (vosoritide) is a C type natriuretic peptide (CNP) analog initially approved by the FDA in November 2021 indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. Achondroplasia is the most common form of skeletal dysplasia with an approximate prevalence of 1 in 20,000 live births. It is an autosomal dominant condition caused by a mutation in the FGFR3 gene which makes the protein that is involved in the development and maintenance of bone and brain tissue.

VOXZOGO (vosoritide) will be considered for coverage when the following criteria are met:

Achondroplasia

For **initial** authorization:

1. Member is at least 5 years of age; AND
2. Medication must be prescribed by or in consultation with a pediatric endocrinologist or geneticist; AND
3. Member has a diagnosis of achondroplasia confirmed by genetic testing showing a FGFR3 gene mutation; AND
4. Member has open epiphyses confirmed by x-ray or tanner stage less than 4; AND
5. Member has baseline growth assessment including standing height and average growth velocity documented in chart notes; AND
6. Member does not have ANY of the following:
   a) History of significant or recurrent hypotension; OR
   b) Has had limb-lengthening surgery in the prior 12 months or is planning to have limb-lengthening surgery in the next 12 months;
7. **Dosage allowed:** Inject subcutaneously once daily per weight-based dosing in package insert
   a) Quantity limit of 30 vials per 30 days
   b) Maximum dose allowed is 0.8 mg (reconstituted) per day

Actual Body Weight	Vial Strength for Reconstitution*	Dose	Injection Volume
10-11 kg	0.4 mg	0.24 mg	0.3 mL
12-16 kg	0.56 mg	0.28 mg	0.35 mL
17-21 kg	0.56 mg	0.32 mg	0.4 mL
22-32 kg	0.56 mg	0.4 mg	0.5 mL
33-43 kg	1.2 mg	0.5 mg	0.25 mL
44-59 kg	1.2 mg	0.6 mg	0.3 mL
60-89 kg	1.2 mg	0.7 mg	0.35 mL
≥90 kg	1.2 mg	0.8 mg	0.4 mL

*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.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Member has open epiphyses confirmed by x-ray or tanner stage less than 4; AND
2. Chart notes must show improvement or stabilized signs and symptoms of disease demonstrated by an increase in average growth velocity

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers VOXZOGO (vosoritide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/26/2022	New policy for Voxzogo created.

References:
1. Voxzogo. Package Insert. BioMarin Pharmaceutical Inc.; 2021. Accessed February 1, 2022. https://voxzogo.com/wp-content/themes/voxzogo/images/prescribing_information.pdf
2. Chan ML, Qi Y, Larimore K, et al. Pharmacokinetics and Exposure-Response of Vosoritide in Children with Achondroplasia [published online ahead of print, 2021 Aug 25]. *Clin Pharmacokinet*. 2021;10.1007/s40262-021-01059-1. doi:10.1007/s40262-021-01059-1
3. Savarirayan R, Irving M, Bacino CA, et al. C-Type Natriuretic Peptide Analogue Therapy in Children with Achondroplasia. N Engl J Med. 2019;381(1):25-35. doi:10.1056/NEJMoa1813446
4. Savarirayan R, Tofts L, Irving M, et al. Once-daily, subcutaneous vosoritide therapy in children with achondroplasia: a randomised, double-blind, phase 3, placebo-controlled, multicentre trial [published correction appears in Lancet. 2020 Oct 10;396(10257):1070]. *Lancet.* 2020;396(10252):684-692. doi:10.1016/S0140-6736(20)31541-5
5. Bacino C. Achondroplasia. In: Post TW, ed. *UpToDate*. UpToDate; 2022. Accessed February 2, 2022. https://www.uptodate.com/contents/achondroplasia
6. Kubota T, Adachi M, Kitaoka T, et al. Clinical Practice Guidelines for Achondroplasia. *Clin Pediatr Endocrinol*. 2020;29(1):25-42. doi:10.1297/cpe.29.25
7. Cormier-Daire V, AlSayed M, Ben-Omran T, et al. The first European consensus on principles of management for achondroplasia. *Orphanet J Rare Dis.* 2021;16(1):333. Published 2021 Jul 31. doi:10.1186/s13023-021-01971-6

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