HAP CareSource™

# PHARMACY POLICY STATEMENT
## HAP CareSource™ Marketplace

| DRUG NAME | Voxzogo (vosoritide) |
|---|---|
| BENEFIT TYPE | Pharmacy |
| STATUS | Prior Authorization Required |

Voxzogo, initially approved by the FDA in 2021, is a C type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients with achondroplasia with open epiphyses. It acts as a positive regulator of endochondral bone growth as it promotes chondrocyte proliferation and differentiation. 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. Medication must be prescribed by or in consultation with a pediatric endocrinologist or geneticist; AND
2. Member has a diagnosis of achondroplasia with a FGFR3 gene mutation confirmed by genetic testing; AND
3. Chart notes include radiographic evidence the member's epiphyses are open (x-ray results must be included); OR
4. Member's tanner stage is less than 4; AND
5. Member has documented baseline growth velocity (cm/yr); AND
6. Member is **NOT** planning to have limb-lengthening surgery. If member has had limb-lengthening surgery it must have been at least 18 months prior to the request.
7. **Dosage allowed/Quantity limit:** Inject subcutaneously once daily per weight-based dosing (see table below). Quantity limit: 30 vials per 30 days.

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| 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 to 16 kg | 0.28 mg | 0.35 mL | 0.56 mg |
| 17 to 21 kg | 0.32 mg | 0.4 mL | 0.56 mg |
| 22 to 32 kg | 0.4 mg | 0.5 mL | 0.56 mg |
| 33 to 43 kg | 0.5 mg | 0.25 mL | 1.2 mg |
| 44 to 59 kg | 0.6 mg | 0.3 mL | 1.2 mg |
| 60 to 89 kg | 0.7 mg | 0.35 mL | 1.2 mg |
| ≥ 90 kg | 0.8 mg | 0.4 mL | 1.2 mg |

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

For **reauthorization**:
1. Chart notes must show an increase in annualized growth velocity (cm/yr); AND
2. Chart notes include radiographic evidence the member's epiphyses are open (x-ray results must be included); OR
3. Member's tanner stage is less than 4.

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

## HAP 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. |
| 11/10/2023 | Removed age requirement; updated references; clarified reauthorization criteria to increase in annual growth velocity; removed baseline standing height requirement; removed absence of hypotension requirement; changed previous limb lengthening surgery from at least 12 to at least 18 months prior to request; updated dosing chart. |

References:


1. Voxzogo [Package Insert]. Novato, CA: BioMarin Pharmaceutical Inc.; 2023.
2. Chan ML, Qi Y, Larimore K, et al. Pharmacokinetics and Exposure-Response of Vosoritide in Children with Achondroplasia. *Clin Pharmacokinet*. 2022;61(2):263-280. 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. 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
6. 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


Effective date: 01/01/2025
Revised date: 11/10/2023