ALASKA MEDICAID
Prior Authorization Criteria

Voxzogo™ (vosoritide)

FDA INDICATIONS AND USAGE[1]

Voxzogo™ is a C type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

APPROVAL CRITERIA[1,2,3,4]

1. Patient's age is ≥ 5 years of age and < 18 years of age **AND**;
2. Prescribed by or in consultation with an endocrinologist or pediatric endocrinologist **AND**;
3. The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene **AND**;
4. Patient's body weight, growth velocity, height, and physical development will be measured at baseline and monitored throughout therapy **AND**;
5. Patient does not have closure of epiphyses **AND**;
6. Patient has not had (within the previous 18 months) nor will they receive limb-lengthening surgery.

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Voxzogo™ is being prescribed concurrently with any human growth hormone product or an insulin-like growth factor **OR**;
3. Other causes of achondroplasia or short stature have not been ruled out (e.g., malnutrition, hypothyroidism, hypercortisolism, hypochondroplasia, thanatophoric dysplasia, SADDAN syndrome, homozygous achondroplasia)

CAUTIONS[1]

- Transient decreases in blood pressure have been reported.
- Monitor growth and adjust dosage according to body weight. Permanently discontinue upon closure of epiphyses.

DURATION OF APPROVAL

- Initial Approval: 6 months
- Reauthorization 12 months with chart notes indicating the patient has had improvements in annualized growth velocity and height compared to pre-treatment baseline.

QUANTITY LIMIT[1]

- 0.4 mg single-dose vial for reconstitution: 1 vial daily
- 0.56 mg single-dose vial for reconstitution: 1 vial daily
- 1.2 mg single-dose vial for reconstitution: 1 vial daily

REFERENCES / FOOTNOTES:

1. Voxzogo™ [prescribing information]. Novato, CA: BioMarin; November 2021.
2. Once-daily, subcutaneous vosoritide therapy in children with achondroplasia: a randomised, double-blind, phase 3, placebo-controlled, multicentre trial. Lancet. 2020;396(10252):684-692.
3. Kubota T, Adachi M, Kitaoka T, et al. Clinical Practice Guidelines for Achondroplasia. Clin Pediatr Endocrinol. 2020;29(1):25-42.
4. Achondroplasia: a comprehensive clinical disease. Orphanet J Rare Dis. 2019;14(1):1.