

Effective date: 05/01/2022
Review date: 2/2022
Scope: Medicaid

## VOXZOGO (vosoritide)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

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).

All other indications are considered experimental/investigational and not medically necessary.

#### II. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for treatment of achondroplasia in members 5 years of age and older when ALL of the following criteria are met:

- A. Prescriber is an endocrinologist, pediatric endocrinologist, geneticist or neurologist.
- B. The diagnosis of achondroplasia was confirmed by genetic testing for FGFR3 mutation.
- C. Documentation of recent annualized growth velocity (AGV).
- D. Recent documentation showing that the patient has open epiphyses and a current AGV of greater than or equal to 1.5cm/year.
- E. Patient has not received growth hormone, insulin-like growth factor 1 or anabolic steroids in the past 6 months.
- F. Patient does not have planned or expected limb lengthening surgery. (Previous limb-lengthening surgery must have occurred at least 18 months prior to administration of Voxzogo).
- G. Member and/or provider has contacted Biomarin and has determined the member is not eligible for a clinical trial (documentation of trial exclusion must be provided).

#### III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continuation of therapy in members 5 years of age and older when all of the following criteria are met:

- A. Chart note documentation showing that the patient has both
  1. Open epiphyses AND
  2. A current AGV of greater than or equal to 1.5cm/year

#### IV. QUANTITY LIMIT

- a. Voxzogo 0.4mg, 0.56mg, 1.2mg: 1 vial per day

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## V. REFERENCES

1. Voxzogo [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; November 2021.
2. Kubota T, Adachi M, Kitaoka T, Hasegawa K, Ohata Y, Fujiwara M, Michigami T, Mochizuki H, Ozono K. Clinical Practice Guidelines for Achondroplasia. Clin Pediatr Endocrinol. 2020;29(1):25-42.
3. Tracy L. Trotter, Judith G. Hall, and the Committee on Genetics. Health Supervision for Children With Achondroplasia. Pediatrics. 2005; 116 (3): 771–783.