Effective date: 05/01/2022
Review date: 2/2022, 3/2023, 2/2024 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 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. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests: Chart notes or documentation of laboratory test reports of genetic testing for FGFR3 mutation and growth chart
B. For continuation requests: Chart notes or medical record documentation confirming benefit from therapy (e.g., growth chart showing improvement or stabilization of annualized growth velocity [centimeters per year])

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for treatment of achondroplasia in pediatric patients 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).

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continuation of therapy in pediatric patients 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

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V. QUANTITY LIMIT

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

VI. REFERENCES

1. Voxzogo [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; October 2023.
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.