Reference number(s)
5069-A

SPECIALTY GUIDELINE MANAGEMENT

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. DOCUMENTATION

Submission of the following information are necessary to initiate the prior authorization review for both initial and continuation of therapy requests:
A. Chart notes or documentation of symptoms (i.e., short stature with marked shortening of extremities due to rhizomelia, a characteristic facial configuration, trident hand) AND X-ray findings consistent with achondroplasia; OR laboratory test reports of genetic testing for FGFR3 mutation
B. Growth chart showing annualized growth velocity (centimeters per year)

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with an endocrinologist, pediatric endocrinologist, geneticist, or neurologist.

IV. 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. The diagnosis of achondroplasia was confirmed by EITHER of the following:
    1. Symptoms (i.e., short stature with marked shortening of extremities due to rhizomelia, a characteristic facial configuration, trident hand) AND X-ray findings consistent with achondroplasia
    2. Genetic testing for FGFR3 mutation
B. Epiphyses are open

V. 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. All criteria for initial approval are met
B. The member's improvement or stabilization of annualized growth velocity (centimeters per year) from baseline

VI. 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.