Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Voxzogo® (vosoritide)**

Effective: September 1, 2023

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Voxzogo (vosoritide) 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 trials.

Clinical Guideline Coverage Criteria

The plan may authorization coverage of Voxzogo for Members when all of the following criteria are met:

Initial Authorization

1. Documented diagnosis of achondroplasia confirmed by genetic testing for the fibroblast growth factor receptor (FGFR) 3 gene mutation

AND

2. The patient is 5 years of age or older

AND

3. Prescribed by or in consultation with an endocrinologist, geneticists, or skeletal dysplasia specialist

AND

4. Documentation of **BOTH** of the following:
   a. The patient is not expected to have limb-lengthening surgery while receiving Voxzogo
   b. If the patient has had previous limb-lengthening surgery, the surgery occurred at least 18 months prior

AND

5. Documentation of open growth plates by radiographical evidence

Reauthorization Criteria

1. Documented diagnosis of achondroplasia confirmed by genetic testing for the fibroblast growth factor receptor (FGFR) 3 gene mutation)

AND

2. The patient is 5 years of age or older

AND

3. Prescribed by or in consultation with an endocrinologist, geneticists, or skeletal dysplasia specialist

AND

4. Documentation the patient has experienced a therapeutic response as defined by an increase in annualized growth velocity from baseline

AND

5. Documentation of **BOTH** of the following:
    a. The patient is not expected to have limb-lengthening surgery while receiving Voxzogo
    b. If the patient has had previous limb-lengthening surgery, the surgery occurred at least 18 months prior

AND

6. Documentation of open growth plates by radiographical evidence

Limitations

1. Initial coverage of Voxzogo (vosoritide) will be authorized for 12 months. Reauthorization of Voxzogo (vosoritide) will be provided for 12-month intervals,
2. Members new to the plan stable on Voxzogo (vosoritide) should be reviewed against Reauthorization Criteria.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Högler W, Ward LM. New developments in the management of achondroplasia. Neue Entwicklungen im Management der Achondroplasie. Wien Med Wochenschr. 2020;170(5-6):104-111.
2. Kubota T, Adachi M, Kitaoka T, et al. Clinical practice guidelines for achondroplasia. Clin Pediatr Endocrinol. 2020;29(1):25-42.
3. Savarirayan R, Irving M, Bacino CA, et al. C-Type natriuretic peptide analogue therapy in children with achondroplasia. N Engl J Med. 2019;381:25-35. doi: 10.1056/NEJMoa1813446.
4. Savarirayan R, Tofts L, Irving M, et al. Once-daily, subcutaneous vosoritide therapy in children with achondroplasia: a randomized, double-blind, phase 3, placebo-controlled, multicentre trial. Lancet. 2020;396(10252):684-692. doi: 10.1016/S0140-6736(20)31541-5.
5. Savarirayan R, Tofts L, Irving M, et al. Safe and persistent growth-promoting effects of vosoritide in children with achondroplasia: 2-year results from an open-label, phase 3 extension study. Genet Med. 2021;23(12):2443-2447. doi: 10.1038/s41436-021-01287-7.
6. Voxzogo (vosoritide). Prescribing information. BioMarin Pharmaceutical Inc.; November 2021. Accessed December 7, 2021.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- June 13, 2023: Added limb-lengthening surgery requirements (effective September 1, 2023).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.