Voxzogo (vosoritide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 6 months Continuation requests: 1 year

Medications	Quantity Limit
Voxzogo (vosoritide)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Voxzogo (vosoritide) may be approved if the following criteria are met:

I. Individual is 5 to 17 years of age; **AND**
II. Individual has a diagnosis of achondroplasia; **AND**
III. Documentation is provided that diagnosis has been confirmed via genetic mutation in fibroblast growth factor receptor 3 (*FGFR3*); **AND**
IV. Documentation is provided that individual has epiphyses that have not yet closed.

Continuation requests for Voxzogo (vosoritide) may be approved if the following criteria are met:

I. There is confirmation of clinically significant improvement in growth velocity; **AND**
II. Documentation is provided that individual has epiphyses that have not yet closed.

Requests for Voxzogo (vosoritide) may not be approved for the following:

I. Individual with an eGFR <60 mL/min/1.73 m2; **OR**
II. Individual using in combination with growth stimulants (growth hormone therapy, insulin-like growth factor 1 or anabolic steroids) (NCT 03197766); **OR**
III. Individual undergoing limb-lengthening surgery (NCT 03197766); **OR**
IV. May not be approved when the above criteria are not met and for all other indications.

Key References:

1. BioMarin Pharmaceutical. A Study to Evaluate the Efficacy and Safety of BMN 111 in Children with Achondroplasia. NLM Identifier: NCT 03197766. Last updated: May 15, 2020. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03197766?term=03197766&draw=2&rank=1. Accessed: February 3, 2022.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: February 3, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Savarirayan R, Tofts L, Irving M, et. al. 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.