JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS147
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Voxzogo

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I. POLICY

A. Voxzogo (vosoritide) will require prior authorization for appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Voxzogo** may be approved for patients meeting the following:
   1. Patient is 5 years of age or older
   2. Documentation has been submitted showing the following:
      a. Patient has a diagnosis of achondroplasia, confirmed by genetic testing showing a mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene
      b. Radiographic evidence indicates the patient has open epiphyses (growth plates)
      c. Baseline measurements include annualized growth velocity (centimeters per year) and body weight
   3. Prescriber is, or has consulted with, an endocrinologist, pediatric endocrinologist, geneticist, or neurologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial therapy may be approved for 6 months
B. Continuation of therapy may be approved in 12-month intervals with documentation showing the following:
   1. Patient's improvement or stabilization of annualized growth velocity (centimeters per year) from baseline
   2. Patient's current body weight
   3. Recent radiographic evidence showing the patient still has open epiphyses (growth plates)

IV. EXCLUSIONS

A. Voxzogo will not be approved for the following:
   1. Concurrent use with Growth Hormone or Insulin-like Growth Factor-1 products
   2. Patients with a decreased growth velocity less than 1.5 cm/yr, or evidence of growth plate closure

3. Patients undergoing, or planning to undergo limb-lengthening surgery while on treatment with Voxzogo
4. Weight-based dosing regimens that are not FDA-approved, or guidelines-supported
5. Any indications for use that are not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Voxzogo [prescribing information]. 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. 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, multicenter trial. Lancet. 2020; 396:684-92.
4. Chan ML, Qi Y, Larimore K, et al. Pharmacokinetics and Exposure-Response of Vosoritide in Children with Achondroplasia. Clin Pharmacokinet. 2022 Feb;61(2):263-280.

VI. APPROVALS

Signature on file at JHHC

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