



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 30, 2022

## **Voxzogo (vosoritide)**

**LENGTH OF AUTHORIZATION:** Up to one year

**REVIEW CRITERIA:**

- Patient must be  $\geq 5$  and  $\leq 16$  years of age; **AND**
- Must be prescribed by an endocrinologist or pediatric endocrinologist **AND**
- Patient must have a diagnosis of achondroplasia confirmed by one of the following:
  - Clinical (e.g., proximal shortening of arms, large head, narrow chest, short fingers) and radiographic (e.g., ilia and horizontal acetabula, narrow sacrosciatic notch, proximal radiolucency of the femurs, generalized metaphyseal abnormality, decreasing interpedicular distance caudally) features consistent with the disorder; **OR**
  - Identification of a heterozygous pathogenic variant in the *FGFR3* gene (e.g., 1138G>A and 1138G>C being the 2 most common), by molecular genetic testing; **AND**
- Confirmation of open growth plates if age 10 and older; **AND**
- Patient body weight, growth velocity, height and physical development will be measured at baseline and monitored throughout therapy; **AND**
- Patient has not had (within the previous 18 months) nor will they receive limb-lengthening surgery **AND**
- Voxzogo is not prescribed concurrently with any human growth hormone products.

**CONTINUATION OF THERAPY:**

- Patient met initial review criteria; **AND**
- Patient does not have closure of epiphyses; **AND**
- Documentation of current weight; **AND**
- Documentation of improvement in annualized growth velocity and height compared to pre-treatment baseline; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

**DOSING AND ADMINISTRATION:**

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as 0.4 mg, 0.56 mg, and 1.2 mg lyophilized powder in single-dose vials for reconstitution.