

SmartPA Criteria Proposal

Drug/Drug Class:	Voxzogo Clinical Edit
First Implementation Date:	TBD
Proposed Date:	March 17, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" type="checkbox"/> New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Voxzogo® (vosoritide)

Why Issue Selected: Voxzogo® (vosoritide) was FDA approved on November 19, 2021 to increase linear growth in pediatric patients with achondroplasia (ACH) and open epiphyses who are at least 5 years of age. ACH is a genetic disorder caused by a pathogenic variant in the *FGFR3* gene, resulting in overactivation of the FGFR3 protein and decreased bone growth. ACH is the most common type of short-limbed dwarfism occurring in roughly 1 in 15,000 to 40,000 newborns worldwide and most commonly presents as shortened limbs, large head circumference, and short stature. Treatment of ACH generally consists of addressing complications (spinal stenosis, recurrent ear infections, obstructive sleep apnea, obesity) and maximizing functional capacity through methods such as physical therapy.

Voxzogo acts by binding to natriuretic peptide receptor-B (NPR-B), resulting in positive regulation of endochondral bone growth by promoting chondrocyte proliferation and differentiation. Voxzogo is the first FDA-approved treatment to increase linear bone growth in patients with ACH and is administered as a once-daily subcutaneous injection.

Due to the high cost and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Voxzogo.

Program-Specific Information:	Drug	Cost per vial (WAC)	Cost per month (WAC)	Cost per year (WAC)
	VOXZOGO 0.4 MG VIAL	\$899.00	\$26,970.00	\$328,135.00
	VOXZOGO 0.56 MG VIAL			
	VOXZOGO 1.2 MG VIAL			

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Voxzogo (vosoritide)
- Age range: All appropriate MO HealthNet participants aged 5 years and older

Approval Criteria

Initial Therapy

- Prescribed by or in consultation with a geneticist, skeletal dysplasia specialist, pediatric endocrinologist, or other specialist in the treated disease state **AND**
- Participant is aged 5 years or older **AND**
- Documented diagnosis of ACH confirmed by genetic testing **AND**
- Documented baseline average growth velocity (AGV) within last 90 days **AND**
- Male participants aged 15 years or older have recent confirmatory X-ray showing open epiphyses **OR**
- Female participants aged 13 years or older have recent confirmatory X-ray showing open epiphyses
- Initial approval for 1 year

Continuation of Therapy

- Documentation of increase in AGV ≥ 1.0 cm/year from baseline **AND**
- Male participants aged 15 years or older have recent confirmatory X-ray showing open epiphyses **OR**
- Female participants aged 13 years or older have recent confirmatory X-ray showing open epiphyses
- Continued approval for 1 year

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant has documented Chronic Kidney Disease (CKD) Stage 3, 4, or 5 or End-Stage Renal Disease
- Participant is currently pregnant
- Claim exceeds 1 vial per day

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

1. Voxzogo (vosoritide) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc; November 2021.
2. IPD Analytics: New Drug Review: Voxzogo (vosoritide). Accessed December 8, 2021.

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7. Johns Hopkins Medicine. Growth Plate Fractures. <https://www.hopkinsallchildrens.org/Patients-Families/Health-Library/HealthDocNew/Growth-Plate-Injuries>. Accessed December 14, 2021.
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