Clinical Policy Title:	vosoritide
Policy Number:	RxA.721
Drug(s) Applied:	Voxzogo™
Original Policy Date:	01/17/2022
Last Review Date:	01/17/2022
Line of Business Policy Applies to:	All lines of business

Background

Vosoritide (Voxzogo™) 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 trial(s).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
vosoritide (Voxzogo™)	Achondroplasia with open epiphyses.	For injection(subcutaneously): 0.4 mg, 0.56 mg, or 1.2 mg lyophilized powder in a single-dose vial for reconstitution.	Varies.

Dosage Forms

- For injection(subcutaneously): 0.4 mg, 0.56 mg, or 1.2 mg lyophilized powder in a single-dose vial for reconstitution.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Achondroplasia with open epiphyses (must meet all):

1. Diagnosis of achondroplasia confirmed through genetic testing;
2. Patient is 5 years of age or older;
3. Voxzogo™ is prescribed by or in consultation with a geneticist, skeletal dysplasia specialists, pediatric endocrinologists;
4. Documentation of recent annualized growth velocity (AGV);
5. Patient has open epiphyses confirmed with imaging and a current AGV of ≥1.5 centimetres/year;
6. Patient has not received previous treatment with growth hormone, insulin-like growth factor 1, or anabolic steroids in the 6 months prior to request;
7. Patient does not have planned or expected limb-lengthening surgery:

a. If patient has had previous limb-lengthening surgery, the surgery must have occurred at least 18 months prior to Voxzogo™ request;

8. Dose does exceed 0.8mg per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Achondroplasia with open epiphyses (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Documentation of a clinically meaningful increase in AGV;
4. Patient has open epiphyses confirmed with imaging and a current AGV of ≥1.5 centimetres/year;
5. Subsequent renewals should require documentation of a continued maintenance of effect on AGV;
6. If request is for a dose increase, new dose does not exceed 0.8mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
AGV: Annualized growth velocity.

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Risk of Low Blood Pressure: To reduce the risk of a decrease in blood pressure and associated symptoms (dizziness, fatigue and/or nausea), instruct patients to be well hydrated and have adequate food intake prior to administration of Voxzogo™.

References

1. Voxzogo™ Prescribing Information. Novato, CA: Biomarin Pharmaceutical Inc; November 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214938s000lbl.pdf. Accessed December 6, 2021.
2. IPD Analytics Rx Insights_New Drug Review_ Voxzogo™ 11.2021. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=+Voxzogo. Accessed December 6, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established	12/06/2021	01/17/2022