Clinical Policy Title:	vosoritide
Policy Number:	RxA.721
Drug(s) Applied:	Voxzogo®
Original Policy Date:	01/17/2022
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of achondroplasia confirmed through genetic testing;
2. Documentation of recent annualized growth velocity;
3. Current growth velocity ≥1.5 centimeters/year and documentation of one of the following (a or b):
   a. Tanner Stage <4;
   b. Recent imaging with evidence of open epiphyses;
4. Patient has not received previous treatment with growth hormone, insulin-like growth factor 1, or anabolic steroids in the 6 months prior to request;
5. 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;
6. Voxzogo is not prescribed concurrently with any human growth hormone products (e.g., Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Zomacton®).

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
2. Current growth velocity ≥1.5 centimeters per year;
3. Documentation of one of the following (a or b):
   a. Tanner stage <4;
   b. Recent imaging with evidence of open epiphyses;
4. Subsequent renewals should require documentation of a continued maintenance of effect on AGV.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Savarirayan, Ravi et al. Once-daily, subcutaneous vosoritide therapy in children with achondroplasia: a randomised, double-blind, phase 3, placebo-controlled, multicentre trial. The Lancet, Volume 396, Issue 10252,

684 – 692. Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31541-5/abstract. Accessed September 4, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established	12/06/2021	01/17/2022
Policy was reviewed 1. Initial Approval Criteria, I.A.5: "Patient has open epiphyses confirmed with imaging and a current AGV of ≥ 1.5 centimetres/year" was replaced with Current growth velocity ≥1.5 centimeters/year and documentation of one of the following (a or b): a. Tanner Stage <4; b. Recent imaging with evidence of open epiphyses. 2. Initial Approval Criteria I.A.8: Updated to add Voxzogo is not prescribed concurrently with any human growth hormone products (e.g., Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Zomacton®); 3. Continued Therapy Approval Criteria II.A.4: "Patient has open epiphyses confirmed with imaging and a current AGV of ≥ 1.5 centimetres/year" was replaced with Current growth velocity ≥ 1.5 centimeters/year and documentation of one of the following (a or b): a. Tanner Stage <4; b. Recent imaging with evidence of open epiphyses.	10/26/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with the new verbiage containing 120 days lookback period. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	8/28/2024	9/13/2024