UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2272-4
Program	Prior Authorization/Medical Necessity
Medication	Voxzogo™ (vosoritide)
P&T Approval Date	3/2022, 3/2023, 12/2023, 12/2024
Effective Date	3/1/2025

1. Background:

Voxzogo (vosoritide) is a C type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients with achondroplasia 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).

Coverage will be provided for members who meet the following criteria.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Voxzogo** will be approved based on **all** of the following criteria:

   a. Patient is less than 18 years of age

   -AND-

   b. Diagnosis of achondroplasia as confirmed by **one** of the following:

      (1) Submission of medical records documenting **both** of the following:

         (a) Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis)

         -AND-

         (b) Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest)

         -OR-

(2) Submission of medical records documenting molecular genetic testing confirmed c.1138G>A or c.1138G>C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene

-AND-

c. Patient has open epiphyses

-AND-

d. **Both** of the following:

(1) Patient has not had limb-lengthening surgery in the previous 18 months
(2) Patient does not plan to have limb-lengthening surgery while on Voxzogo

-AND-

e. Prescribed by **one** of the following:

(1) Clinical geneticist
(2) Endocrinologist
(3) A practitioner who has specialized expertise in the management of achondroplasia

Authorization will be issued for 12 months.

B. Reauthorization

1. **Voxzogo** will be approved based on **all** the following criteria:

a. Documentation of positive clinical response to Voxzogo therapy (e.g., improvement in annualized growth velocity (AGV) compared to baseline)

-AND-

b. Patient has open epiphyses

-AND-

c. Patient does not plan to have limb-lengthening surgery while on Voxzogo

-AND-

d. Prescribed by or in consultation with **one** of the following:

(1) Clinical geneticist
(2) Endocrinologist
(3) A practitioner who has specialized expertise in the management of achondroplasia

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Voxzogo [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; October 2023.
2. Pauli RM. Achondroplasia: a comprehensive clinical review. Orphanet J Rare Dis 2019;14(1):1-49.
3. Hoover-Fong J, Scott CI, Jones MC; COMMITTEE ON GENETICS. Health Supervision for People With Achondroplasia. *Pediatrics*. 2020;145(6):e20201010.

Program	Prior Authorization/Medical Necessity – Voxzogo (vosoritide)
Change Control	
3/2022	New program
3/2023	Annual review with no changes to coverage criteria. Updated references.
12/2023	Updated background and coverage criteria with expanded indication in pediatric patients of all ages. Updated references.
12/2024	Annual review. Updated wording of open epiphyses requirement in reauthorization criteria with no change to clinical intent. Updated references.