MEDICAL MUTUAL®

# Drug Policy

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| **Policy:** | **010122** | **Initial Effective Date:** |
| **Code(s):** | **HCPCS J3490, C9399** | **Annual Review Date: 11/21/2023** |
| **SUBJECT:** | Voxzogo™ (vosoritide subcutaneous injection) | **Last Revised Date: 11/21/2023** |

**Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.**

## POLICY STATEMENT

This policy involves the use of Voxzogo. Prior authorization is recommended for pharmacy and medical benefit coverage of Voxzogo. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing (medical benefit requests only), and Initial/Extended Approval** for the diagnosis provided. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Voxzogo as well as the monitoring required for AEs and long-term efficacy, initial approval requires Voxzogo be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

The site of care medical necessity criteria applies to initial therapy and reauthorizations under the medical benefit only.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Voxzogo is recommended in those who meet the following criteria:

### FDA-Approved Indications

1. **Achondroplasia.** Approve for 1 year if the patient meets ONE of the following criteria (A or B):
   - **A)** Initial Therapy or Patient Has Been on Voxzogo < 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
     - **i.** Patient is < 18 years of age; AND
     - **ii.** The patient weighs at least 3 kg; AND
     - **iii.** The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene; AND
     - **iv.** Patient's epiphyses are open; AND
     - **v.** Patient will not have limb-lengthening surgery during treatment with Voxzogo; AND

**vi.** The prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration; AND
**vii.** The medication is prescribed by or in consultation with a pediatric endocrinologist.

**B)** Patient Has Been Receiving Voxzogo for ≥ 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, vi, vii, and viii):
**i.** Patient is < 18 years of age; AND
**ii.** The patient weighs at least 3 kg; AND
**iii.** The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene; AND
**iv.** Patient's epiphyses are open; AND
**v.** Patient will not have limb-lengthening surgery during treatment with Voxzogo; AND
**vi.** The prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration; AND
**vii.** The medication is prescribed by or in consultation with a pediatric endocrinologist; AND
**viii.** Patient's most recent annualized growth velocity continues to be above their baseline annualized growth velocity value (i.e., before the patient started on Voxzogo).

**Dosing in Voxzogo.** *Dosing must meet the following (medical benefit only):*

- Recommended dosage is based on patient's actual body weight and administered subcutaneously once daily.

| ABW* | Dose | Injected Volume | Vial Strength for Reconstitution** |
|---|---|---|---|
| 3 kg | 0.096 mg | 0.12 mL | 0.4 mg |
| 4 kg | 0.12 mg | 0.15 mL | 0.4 mg |
| 5 kg | 0.16 mg | 0.2 mL | 0.4 mg |
| 6 to 7 kg | 0.2 mg | 0.25 mL | 0.4 mg |
| 8 to 11 kg | 0.24 mg | 0.3 mL | 0.4 mg |
| 12 to 16 kg | 0.28 mg | 0.35 mL | 0.56 mg |
| 17 to 21 kg | 0.32 mg | 0.4 mL | 0.56 mg |
| 22 to 32 kg | 0.4 mg | 0.5 mL | 0.56 mg |
| 33 to 43 kg | 0.5 mg | 0.25 mL | 1.2 mg |
| 44 to 59 kg | 0.6 mg | 0.3 mL | 1.2 mg |
| 60 to 89 kg | 0.7 mg | 0.35 mL | 1.2 mg |
| ≥90 kg | 0.8 mg | 0.4 mL | 1.2 mg |

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 12 months (365 days)
**B)** *Extended Approval:* 12 months (365 days)

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Voxzogo is not recommended in the following situations:

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1. **Hypochondroplasia, Thanatophoric Dysplasia, or other Short Stature Conditions other than Achondroplasia (e.g., trisomy 21, pseudoachondroplasia).** Voxzogo is only indicated for patients with achondroplasia.[1] There is no evidence Voxzogo is effective for other short stature conditions.

2. **Concurrent Treatment with Growth Hormone (e.g., somatropin), Long-Acting Growth Hormone (e.g., Ngenla® {somatrogon-ghla}, Skytrofa® {lonapegsomatropin}, Sogroya® {somapacitan-beco}), or Insulin-like Growth Factor- 1 (IGF-1) [i.e., Increlex® {mecasermin}] Agents.** Growth hormone agents and Increlex are NOT indicated to increase growth in patients with achondroplasia.[6,7,8] Additionally, there are no available studies demonstrating the safety or efficacy of concurrent use with Voxzogo.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES


1. Voxzogo™ subcutaneous injection [prescribing information]. Novato, CA: BioMarin; October 2023.
2. Once-daily, subcutaneous vosoritide therapy in children with achondroplasia: a randomised, double-blind, phase 3, placebo-controlled, multicentre trial. Lancet. 2020;396(10252):684-692.
3. National Organization for Rare Disorders (NORD). Achondroplasia Last updated December 8, 2021. Available at: Achondroplasia - NORD (National Organization for Rare Disorders) (rarediseases.org). Accessed on October 30, 2023.
4. Achondroplasia: a comprehensive clinical disease. Orphanet J Rare Dis. 2019;14(1):1.
5. Health supervision for people with achondroplasia. American Academy of Pediatrics. Pediatrics. 2020;145(6):e20201010.
6. Norditropin® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; March 2020.
7. Skytrofa™ subcutaneous injection [prescribing information]. Palo Alto, CA: Ascendis; October 2022.
8. Sogroya® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; April 2023.
9. Ngenla® subcutaneous injection [prescribing information]. New York, NY: Pfizer; June 2023.
10. Increlex® subcutaneous injection [prescribing information]. Cambridge, MA: Ipsen; October 2023.


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## FOR MEDICAL BENEFIT COVERAGE REQUESTS:

### MMO Site of Care Medical Necessity Criteria:

- Medications in this policy will be administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless *at least one* of the following are met†:

    1. Age less than 18 years*; or
    2. Clinically unstable based upon documented medical history (e.g., patient is hemodynamically unstable); or
    3. History of a severe adverse event from previous administration of the prescribed medication; or
    4. Requested medication is being administered as follows:
        - part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer; or
        - administered with dialysis; or
    5. Physical or cognitive impairment and caregiver is not available to assist with safe administration of prescribed medication in the home; or
    6. Experiencing adverse events that are not managed by premedication or resources available at a non-hospital facility based location.

* Effective 01/01/2019, age criterion applies to 18 years of older. Age at original effective date (03/01/2016) was 21 years or older.
†This criterion does not apply to Medicare or Medicare Advantage members.

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**Prior approval is required for HCPCS Codes J3490 or C9399**

**†When *unclassified drugs* (J3490) or *unclassified drugs or biologics [hospital outpatient use only]* (C9399) is determined to be Voxzogo**