

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: select one drug below

☐ **Voxzogo®** (vosoritide)

☐ **Yuviwel®** (navepegritide)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

A. Voxzogo:

- **Quantity Limit:** Maximum approval of 1 vial per day and maximum dose of 1.2 mg daily
- **Recommended Dosage:** Weight-based dosing will be approved based on dosing guidelines as follows:

Actual Body Weight	Vial Strength for Reconstitution*	Dose	Injection Volume
10-11 kg	0.4 mg	0.24 mg	0.3 mL
12-16 kg	0.56 mg	0.28 mg	0.35 mL
17-21 kg	0.56 mg	0.32 mg	0.4 mL
22-32 kg	0.56 mg	0.4 mg	0.5 mL
33-43 kg	1.2 mg	0.5 mg	0.25 mL
44-59 kg	1.2 mg	0.6 mg	0.3 mL
60-89 kg	1.2 mg	0.7 mg	0.35 mL
≥ 90 kg	1.2 mg	0.8 mg	0.4 mL

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B. Yuviwel:

- **Quantity Limit:** Maximum approval of 4 kits per month for 1.3 mg and 2.8 mg strengths & 8 kits per month for 5.5 mg strength
- **Recommended Dosage:** Weight-based dosing will be approved based on dosing guidelines as follows:

Actual Body Weight	Weekly dose	Dose Volume	Vial strength needed for reconstitution	Reconstituted concentration
8 to <10 kg	0.88 mg once weekly	0.4 mL	1.3 mg/vial	2.2 mg/mL
10 to <13.5 kg	1.2 mg once weekly	0.55 mL		
13.5 to <17.6 kg	1.6 mg once weekly	0.35 mL	2.8 mg/vial	4.6 mg/mL
17.6 to <23.1 kg	2.1 mg once weekly	0.45 mL		
23.1 to <30.6 kg	2.8 mg once weekly	0.6 mL		
30.6 to <41.3 kg	3.6 mg once weekly	0.65 mL	5.5 mg/vial	5.5 mg/mL
41.3 to <56 kg	5 mg once weekly	0.9 mL		
56 to <73.6 kg	6.6 mg once weekly	1.2 mL (use 2 kits)		
73.6 to 90 kg	8.8 mg once weekly	1.6 mL (use 2 kits)		

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ☐ Provider is an endocrinologist or metabolic geneticist specializing in treatment of achondroplasia
- ☐ Member must meet **ONE** of the following:
 - ☐ For Voxzogo requests: Member is < 18 years of age
 - ☐ For Yuviwel requests: Member is 2 to < 18 years of age
- ☐ Member has a diagnosis of achondroplasia confirmed by **BOTH** of the following:
 - ☐ Clinical (e.g., proximal shortening of arms, large head, narrow chest, short fingers) and radiographic (e.g., ilia and horizontal acetabula, narrow sacrosciatic notch, proximal radiolucency of the femurs, generalized metaphyseal abnormality, decreasing interpedicular distance caudally) features consistent with the disorder
 - ☐ Identification of a heterozygous pathogenic variant in the FGFR3 gene (e.g., c.1138G>A and c.1138G>C being the two most common) by molecular genetic testing (**submit test results**)
- ☐ Member has **NOT** had (within the previous 18 months), nor will they receive limb-lengthening surgery
- ☐ Other causes of achondroplasia or short stature have been ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism, hypochondroplasia, thanatophoric dysplasia, SADDAN syndrome, homozygous achondroplasia [excludes approved labeled indication])

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- ☐ Requested medication will **NOT** be used in combination with growth hormone (e.g., somatropin), or growth hormone analogs (e.g., somapacitan) or insulin-like growth factor (IGF-1) (e.g., mecasermin)
- ☐ Member's epiphyses are still open (**submit current bone x-ray confirming open epiphyses**)
- ☐ Member's estimated glomerular filtration rate (eGFR) is ≥ 60 mL/min/1.73m²
- ☐ Member's current height _____ **AND** weight _____ **must be provided**
- ☐ Member does **NOT** have a history of significant cardiac or vascular disease and is not currently taking any medications to treat hypertension
- ☐ Member will be regularly monitored for transient hypotensive events while using requested medication
- ☐ **For Yuviwel requests:** Member has had trial and intolerable life-endangering adverse event with vosoritide (Voxzogo) (**must submit completed MedWatch form and chart notes to document adverse event**)
- ☐ Member will **NOT** use vosoritide (Voxzogo®) concomitantly with navepegritide (Yuviwel®)

Reauthorization: 12 months. Check below all that apply. All criteria must be checked for approval. To support each line checked, all documentation, including (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ☐ Member continues to meet all initial authorization criteria
- ☐ Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe hypotension, severe injection site reactions)
- ☐ Member did **NOT** have closure of epiphyses or decreased growth velocity (< 1.5 cm per year) since last approval of medication (**submit current bone x-ray documentation**)
- ☐ Member has shown a beneficial response to treatment as evidenced by **BOTH** of the following:
 - ☐ Annualized growth velocity is ≥ 1.5 cm/year
 - ☐ Improvement in height compared to last measurement (**within the past 6 months**)
- ☐ Member's current height _____ **AND** weight _____ **must be provided**
- ☐ Member will **NOT** use vosoritide (Voxzogo®) concomitantly with navepegritide (Yuviwel®)

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****