

DRUG POLICY

Voxzogo® (vosoritide) and Yuviwel™ (navepegritide)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Voxzogo (vosoritide) is 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).

Yuviwel (navepegritide) is indicated to increase linear growth in pediatric patients 2 years of age and older 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).

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Chart notes or documentation of symptoms (i.e., short stature with marked shortening of extremities due to rhizomelia, a characteristic facial configuration, trident hand) if applicable
2. Laboratory report of X-ray findings consistent with achondroplasia OR laboratory report of genetic testing for FGFR3 mutation
3. Growth chart, chart notes, or medical record documentation showing heights and growth velocities

4. For continuation requests: Chart notes or medical record documentation confirming benefit from therapy (e.g., growth chart showing improvement or stabilization of annualized growth velocity [centimeters per year])

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Endocrinologist
2. Pediatric endocrinologist
3. Geneticist
4. Neurologist.

Criteria for Initial Approval

Achondroplasia

1. Authorization of 12 months may be granted for treatment of achondroplasia when ALL of the following criteria are met:
 - A. The diagnosis of achondroplasia was confirmed by EITHER of the following:
 - i. Symptoms (i.e., short stature with marked shortening of extremities due to rhizomelia, a characteristic facial configuration, trident hand) AND X-ray findings consistent with achondroplasia
 - ii. Genetic testing for FGFR3 mutation
 - B. Epiphyses are open
 - C. Member is 2 years of age or older (Yuviwel only)

Continuation of Therapy

Achondroplasia

1. Authorization of 12 months may be granted for continuation of therapy when ALL of the following criteria are met:
 - A. All criteria for initial approval are met
 - B. The member is experiencing benefit from therapy (e.g., improvement or stabilization of annualized growth velocity [centimeters per year] from baseline)
 - C. Member is 2 years of age or older (Yuviwel only)

Other

Voxzogo® (vosoritide) and Yuviwel (navepegritide) are considered **not medically necessary** for members who do not meet the criteria set forth above.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure,

severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing			
Voxzogo single-dose vial 0.4 mg	30 per 30 days	Subcutaneous injection once daily based on patient's actual body weight:			
Voxzogo single-dose vial 0.56 mg	30 per 30 days	<u>Actual Body Weight</u>	<u>Vial strength for reconstitution</u>	<u>Dose</u>	<u>Injection Volume</u>
Voxzogo single-dose vial 1.2 mg	30 per 30 days	3 kg	0.4 mg	0.096 mg	0.12 mL
		4 kg	0.4 mg	0.12 mg	0.15 mL
		5 kg	0.4 mg	0.16 mg	0.2 mL
		6-7 kg	0.4 mg	0.2 mg	0.25 mL
		8-11 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
Yuwiwel single-dose vial 1.3 mg	4 per 28 days	Subcutaneous injection once daily based on patient's actual body weight:			
Yuwiwel single-dose vial 2.8 mg	4 per 28 days	<u>Actual Body Weight</u>	<u>Vial strength for reconstitution</u>	<u>Weekly Dose</u>	<u>Injection Volume</u>
Yuwiwel single-dose vial 5.5 mg	4 per 28 days	8-9.9 kg	1.3 mg	0.88 mg	0.4 mL
		10-13.4 kg	1.3 mg	1.2 mg	0.55 mL
		13.5-17.5 kg	2.8 mg	1.6 mg	0.35 mL
		17.6-23 kg	2.8 mg	2.1 mg	0.45 mL
		23.1-30.5 kg	2.8 mg	2.8 mg	0.6 mL
		30.6-41.2 kg	5.5 mg	3.6 mg	0.65 mL
		41.3-55.9 kg	5.5 mg	5 mg	0.9 mL
		56-73.5 kg	5.5 mg	6.6 mg	1.2 mL
		73.6-90 kg	5.5 mg	8.8 mg	1.6 mL

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

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POLICY HISTORY

Policy #: 05.04.51

Original Effective Date: March 13, 2022

Reviewed: June 2026

Revised: June 2026

Current Effective Date: August 21, 2026