Effective Date: 11/01/2026
Reviewed: 08/2026
Scope: Medicaid

Yuviwel (navepegritide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
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).

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR APPROVAL

Authorization of 6 months may be granted for treatment of achondroplasia in pediatric members when ALL of the following criteria are met:

A. Member is 2 years of age or older.
B. Documentation of member's weight.
C. Prescriber is an endocrinologist, pediatric endocrinologist, geneticist, or neurologist.
D. Documentation that diagnosis of achondroplasia was confirmed by genetic testing for FGFR3 mutation.
E. Documentation of recent annualized growth velocity (AGV).
F. Recent documentation showing that the member has open epiphyses and a current AGV of greater than or equal to 1.5cm/year.
G. Documentation that the member has not received growth hormone, insulin-like growth factor 1 or anabolic steroids in the past 6 months.
H. Documentation that the member does not have planned or expected limb lengthening surgery. (Previous limb-lengthening surgery must have occurred at least 18 months prior to administration of Yuviwel).
I. Member is not using Yuviwel in combination with Voxzogo.
J. Members new to Yuviwel treatment who weigh 56 kg or greater must have a documented treatment failure, contraindication, or intolerance to Voxzogo.

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continuation of therapy in pediatric members when ALL of the following criteria are met:

A. If member has not been approved for this drug by Neighborhood in the past, clinician must submit documentation that initial criteria is met.
B. Documentation of member's weight.
C. Chart note documentation showing that the member has both:
    1. Open epiphyses AND
    2. A current AGV of greater than or equal to 1.5 cm/year

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IV. QUANTITY LIMIT

Yuviwel 1.3 mg, 2.8 mg, and 5.5 mg vials have a quantity limit of 1 vial per 7 days (daily dose of 0.15).

A quantity limit exception will be provided for a dose of 2 vials per 7 days (daily dose of 0.29) for members with a documented body weight of ≥56 kg who require a weekly dose of 6.6 mg or 8.8 mg.

Table 1: Recommended YUVIWEL Weekly Dosage and Injection Volume

Patient Body weight	Weekly Dose	Injection Volume	Vial Strength for Reconstitution*
8 to 9.9 kg	0.88 mg	0.4 mL	1.3 mg
10 to 13.4 kg	1.2 mg	0.55 mL	
13.5 to 17.5 kg	1.6 mg	0.35 mL	2.8 mg
17.6 to 23 kg	2.1 mg	0.45 mL	
23.1 to 30.5 kg	2.8 mg	0.6 mL	
30.6 to 41.2 kg	3.6 mg	0.65 mL	5.5 mg
41.3 to 55.9 kg	5 mg	0.9 mL	
56 to 73.5 kg	6.6 mg	1.2 mL (use 2 Kits) Administer 0.6 mL from each Kit	
73.6 to 90 kg	8.8 mg	1.6 mL (use 2 Kits) Administer 0.8 mL from each Kit	

*The concentration of navepegritide is 2.2 mg/mL in a reconstituted 1.3 mg vial; 4.6 mg/mL in a reconstituted 2.8 mg vial; and 5.5 mg/mL in a reconstituted 5.5 mg vial.

V. REFERENCES

1. Yuviwel [package insert]. Princeton, NJ: Ascendis Pharma Endocrinology, Inc.; February 2026.
2. Kubota T, Adachi M, Kitaoka T, et al. Clinical Practice Guidelines for Achondroplasia. Clin Pediatr Endocrinol. 2020;29(1):25-42.
3. Trotter TL, Hall JG, American Academy of Pediatrics Committee on Genetics. Health supervision for children with achondroplasia. Pediatrics. 2005;116(3):771-783.
4. Hoover-Fong J, Scott CI, Jones MC, Committee on Genetics. Health supervision for people with achondroplasia. Pediatrics. 2020;145(6):e20201010.
5. Savarirayan R, Ireland P, Irving M, et al. International Consensus Statement on the diagnosis, multidisciplinary management and lifelong care of individuals with achondroplasia. Nat Rev Endocrinol. 2022;18:173-189.
6. National Organization for Rare Disorders (NORD). Achondroplasia. Available at https://rarediseases.org/rare-diseases/achondroplasia/. Last updated November 17, 2023. Accessed on March 4, 2026.