

Clinical Policy: Navepegritide (Yuviwel)

Reference Number: CP.PHAR.746

Effective Date: 02.27.26

Last Review Date: 08.26

Line of Business: Commercial, HIM/ICHRA, Medicaid

[Coding Implications](#)[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Navepegritide (Yuviwel®) is a prodrug of C-type natriuretic peptide (CNP).

FDA Approved Indication(s)

Yuviwel 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/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Yuviwel is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Achondroplasia (must meet all):**

1. Diagnosis of achondroplasia with genetic testing confirming a mutation in the fibroblast growth factor receptor 3 (FGFR3) gene;
 2. Prescribed by or in consultation with a pediatric endocrinologist;
 3. Age ≥ 2 and < 12 years;
 4. At the time of request, radiographic evidence indicates open epiphyses (growth plates);
 5. Failure of Voxzogo®, unless contraindicated or clinically significant adverse effects are experienced;*
- *For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
6. Documentation of baseline annualized growth velocity, calculated based on standing height measured over the course of 6 months prior to request;
 7. Documentation of member's current weight (in kg);
 8. Member will not have limb-lengthening surgery during treatment with Yuviwel;
 9. Yuviwel is not prescribed concurrently with any human growth hormone products (e.g., Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Zomacton®);
 10. Yuviwel is not prescribed concurrently with Voxzogo;

11. Dose does not exceed both of the following (a and b):
 - a. Weight-based weekly dosing (*see Section V. Dosage and Administration*);
 - b. One of the following (i or ii):
 - i. 1 vial per week;
 - ii. Weight 56 to 90 kg: 2 vials per week.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Achondroplasia (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy as evidenced by improvement in annualized growth velocity from baseline;
3. Radiographic evidence within the last four months indicates that the member continues to have open epiphyses (growth plates);
4. Member will not have limb-lengthening surgery during treatment with Yuviwel;
5. Yuviwel is not prescribed concurrently with any human growth hormone products (e.g., Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zomacton);
6. Yuviwel is not prescribed concurrently with Voxzogo;
7. Documentation of member's current weight (in kg);
8. If request is for a dose increase, new dose does not exceed both of the following (a and b):
 - a. Weight-based weekly dosing (*see Section V. Dosage and Administration*);

- b. One of the following (i or ii):
 - i. 1 vial per week;
 - ii. Weight 56 to 90 kg: 2 vials per week.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CNP: C-type natriuretic peptide

FDA: Food and Drug Administration

FGFR3: fibroblast growth factor receptor 3

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Voxzogo (vosoritide)	Dose is a once-daily SC injection based on actual body weight: • 3 kg: 0.096 mg/day • 4 kg: 0.12 mg/day • 5 kg: 0.16 mg/day	Varies per actual body weight

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	• 6-7 kg: 0.2 mg/day • 8-11 kg: 0.24 mg/day • 12-16 kg: 0.28 mg/day • 17-21 kg: 0.32 mg/day • 22-32 kg: 0.4 mg/day • 33-43 kg: 0.5 mg/day • 44-59 kg: 0.6 mg/day • 60-89 kg: 0.7 mg/day • ≥ 90 kg: 0.8 mg/day	

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Achondroplasia	SC once weekly based on body weight: • 8 to 9.9 kg: 0.88 mg/week • 10 to 13.4 kg: 1.2 mg/week • 13.5 to 17.5 kg: 1.6 mg/week • 17.6 to 23 kg: 2.1 mg/week • 23.1 to 30.5 kg: 2.8 mg/week • 30.6 to 41.2 kg: 3.6 mg/week • 41.3 to 55.9 kg: 5 mg/week • 56 to 73.5 kg: 6.6 mg/week • 73.6 to 90 kg: 8.8 mg/week	See dosing regimen

VI. Product Availability

Single-dose vials with lyophilized powder: 1.3 mg, 2.8 mg, 5.5 mg

VII. References

1. Yuviwel Prescribing Information. Hellerup, Denmark; Ascendis Pharma Growth Disorders A/S. February 2026. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/219164Orig1s000lbl.pdf. Accessed March 9, 2026.
2. Ascendis Pharma: TransCon[™] CNP (navepegritide) ApproaCH Trial Topline Results. September 16, 2024. Available at: <https://investors.ascendispharma.com/static-files/ac6e8fb8-8ab9-4c5c-b25c-14a90f766b48>. Accessed July 31, 2025.
3. A clinical trial to evaluate efficacy and safety of TransCon CNP compared with placebo in children with achondroplasia (ApproaCH). ClinicalTrials.gov, identifier NCT05598320. Available at: <https://clinicaltrials.gov/study/NCT05598320>. Accessed July 31, 2025.

4. Savarirayan R, Hoernschemeyer DG, Ljungberg M, et al. Once-weekly TransCon CNP (navepegritide) in children with achondroplasia (ACcomplisH): a phase 2, multicentre, randomised, double-blind, placebo-controlled, dose-escalation trial. *Lancet*. 2023; 65: 1-10.
5. A dose escalation trial evaluating safety, efficacy, and pharmacokinetics of TransCon CNP administered once weekly in prepubertal children with achondroplasia. ClinicalTrials.gov, identifier NCT04085523. U.S. National Library of Medicine, May 22, 2025. Available at: <https://clinicaltrials.gov/study/NCT04085523>. Accessed July 30, 2025.
6. Hoover-Fong J, Scott CI, Jones MC, AAP Committee on Genetics. Health supervision for people with achondroplasia. *Pediatrics*. 2020;145(6):e20201010.
7. 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(3):173-189.
8. Savarirayan R, McDonnell C, Bacino CA, et al. Once-weekly navepegritide in children with achondroplasia: The APPROACH randomized clinical trial. *JAMA Pediatr*. 2026;180(1):18-25. doi:10.1001/jamapediatrics.2025.4771
9. Savarirayan R, Bacino C, McDonnell C, et al. 004: Growth outcomes and safety of navepegritide in children with achondroplasia: 2-year results of the ApproaCH trial open-label extension. *Genetics in Medicine Open*. 2026; 4(1). <https://doi.org/10.1016/j.gimo.2026.104288>

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	07.30.25	11.25
RT1: Drug is now FDA approved – criteria updated per prescribing information to include weight-based dosing and quantity limits; added to continued therapy requirement that Yuviwel is not prescribed concurrently with Voxzogo and any human growth hormone products; added ICHRA line of business; references reviewed and updated.	04.07.26	05.26
Per June SDC, added requirement that member will not have limb-lengthening surgery during treatment and added redirection to Voxzogo.	06.09.26	08.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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