Medical Drug Clinical Criteria

Subject:	Yuviwel (navepegritide)		
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Overview

This document addresses the use of Yuviwel (navepegritide), a C-type natriuretic peptide (CNP) analog approved by the Food and Drug Administration (FDA) to increase linear growth in pediatric individuals 2 years of age and older with achondroplasia and open epiphyses. The dose of Yuviwel is based on body weight and is administered via subcutaneous injection once weekly. Growth and physical development should be monitored regularly, and Yuviwel should be permanently discontinued upon closure of epiphyses.

The safety and efficacy of Yuviwel was evaluated in 84 pediatric individuals with achondroplasia in a 52-week, randomized, double-blind, placebo-controlled phase 3 study. Participants had genetically-confirmed achondroplasia and open epiphyses and were randomized to either Yuviwel or placebo. Yuviwel demonstrated a statistically significant improvement in annualized growth velocity (AGV) of 1.5 cm/year compared with placebo. Yuviwel was approved under an accelerated pathway based on an improvement in AGV, and continued approval may be contingent upon verification of clinical benefit (pubertal growth velocity, body segment proportionality, final adult height, achondroplasia-associated complications) in confirmatory trials.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Yuviwel (navepegritide)

Initial requests for Yuviwel (navepegritide) may be approved if the following criteria are met:

I. Individual is 2 to 17 years of age; **AND**
II. Individual has a diagnosis of achondroplasia; **AND**
III. Documentation is provided that diagnosis has been verified via genetic mutation in fibroblast growth factor receptor 3 (*FGFR3*); **AND**
IV. Documentation is provided that individual has open epiphyses.

Continuation requests for Yuviwel (navepegritide) may be approved if the following criteria are met:

I. There is clinically significant improvement in annualized growth velocity; **AND**
II. Documentation is provided that individual has open epiphyses.

Requests for Yuviwel (navepegritide) may not be approved for the following:

I. Individual using in combination with Voxzogo (vosoritide) or growth stimulants (growth hormone therapy, insulin-like growth factor 1 or anabolic steroids); **OR**
II. Individual undergoing limb-lengthening surgery while on Yuviwel therapy; **OR**
III. May not be approved when the above criteria are not met and for all other indications.

Approval Duration
Initial Requests: 6 months
Continuation Requests: 12 months

Quantity Limits

Yuviwel (navepegritide) Quantity Limits

Drug	Limit
Yuviwel (navepegritide) 1.3 mg, 2.8 mg, 5.5 mg single-dose vial	4 kits (4 vials) per 28 days
Override Criteria	
May approve Yuviwel (navepegritide) 5.5 mg 8 kits (8 vials) per 28 days for individuals weighing 56 kg or greater.	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as Yuviwel (navepegritide)]
J3490	Unclassified drugs [when specified as Yuviwel (navepegritide)]

ICD-10 Diagnosis

Q77.4	Achondroplasia

Document History

New: 3/9/2026
Document History:

- 3/9/2026 – Annual Review: New clinical criteria and quantity limit for Yuviwel. Administrative update to add documentation. Coding Reviewed: Added HCPCS NOC C9399, J3490, and ICD-10-CM Q77.4 for Yuviwel.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 8, 2026.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. 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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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