Drug Coverage Policy

Effective Date.....8/15/2026
Coverage Policy Number.....IP0799
Policy Title..... Growth Disorders – Yuviwel

Growth Disorders – Yuviwel

- Yuviwel® (navepegritide subcutaneous injection – Ascendis)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW
Yuviwel, a C-type natriuretic peptide (CNP) analog, is indicated **to increase linear growth in pediatric patients ≥ 2 years of age with achondroplasia** with open epiphyses.[1]

Disease Overview

Achondroplasia is a skeletal dysplasia characterized by disproportionate short stature in humans.[2] It is a rare genetic condition arising from a pathogenic fibroblast growth factor receptor 3 (FGFR3) variant. Achondroplasia occurs in approximately 1 in 20,000 to 30,000 live births.[3] It occurs as a result of a spontaneous mutation in 80% of patients (i.e., both parents are of normal height).[4] In the remaining 20% of patients, the mutation is inherited from a parent. Achondroplasia is characterized by short stature, long-bone shortening in the proximal upper and lower extremities, and macrocephaly. The diagnosis can be confirmed by molecular testing.[5] In the pivotal trial for Yuviwel, achondroplasia was confirmed by genetic testing in all patients.[2]

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POLICY STATEMENT

Prior Authorization is required for benefit coverage of Yuviwel. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Yuviwel as well as the monitoring required for adverse events and long-term efficacy, approval requires Yuviwel to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, prescription receipts and/or other information. All documentation must include patient-specific identifying information.

Yuviwel is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Achondroplasia.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy or Patient Has Been on Yuviwel for < 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 2 years of age AND < 18 years of age; AND
     - **ii.** The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable pathogenic variant in the fibroblast growth factor receptor type 3 (FGFR3) gene **[documentation required];** AND
     - **iii.** Patient's epiphyses are open; AND
     - **iv.** Patient will not have limb-lengthening surgery during treatment with Yuviwel; AND
     - **v.** The medication is prescribed by or in consultation with a pediatric endocrinologist; OR
   - **B)** Patient Has Been Receiving Yuviwel for ≥ 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
     - **i.** Patient is ≥ 2 years of age AND < 18 years of age; AND
     - **ii.** The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable pathogenic variant in the fibroblast growth factor receptor type 3 (FGFR3) gene **[documentation required]**; AND
     - **iii.** Patient's epiphyses are open; AND
     - **iv.** Patient will not have limb-lengthening surgery during treatment with Yuviwel; AND
     - **v.** The medication is prescribed by or in consultation with a pediatric endocrinologist; AND
     - **vi.** Patient's most recent annualized growth velocity continues to be above their baseline annualized growth velocity value (i.e., before the patient started on Yuviwel or Voxzogo™ [vosoritide injection]).

Conditions Not Covered

Yuviwel for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Hypochondroplasia, Thanatophoric Dysplasia, or other Short Stature Conditions other than Achondroplasia (e.g., Trisomy 21, Pseudoachondroplasia).** Yuviwel is only indicated for patients with achondroplasia.[1] There is no evidence Yuviwel is effective for other short stature conditions.

2. **Concurrent Treatment with Voxzogo (vosoritide injection), Growth Hormone (e.g., somatropin), Long-Acting Growth Hormone (e.g., Ngenla® [somatrogon-ghla], Skytrofa® [lonapegsomatropin], Sogroya® [somapacitan-beco]), or Insulin-like Growth Factor- 1 (IGF-1) [i.e., Increlex® {mecasermin}] Agents.** Growth hormone agents and Increlex are NOT indicated to increase growth in patients with achondroplasia.[6-10] Additionally, there are no available studies demonstrating the safety or efficacy of concurrent use with Yuviwel.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics

References

1. Yuviwel® subcutaneous injection [prescribing information]. Princeton, NJ: Ascendis; February 2026.
2. Savarirayan R, McDonnell C, Bacino C, et al. Once-weekly navepegritide in children with achondroplasia: The APPROACH randomized clinical trial. *JAMA Pediatr.* 2026;180(1):18-25.
3. National Organization for Rare Disorders (NORD). Rare Disease Information. Available at: Achondroplasia - NORD (National Organization for Rare Disorders) (rarediseases.org). Accessed on March 8, 2026.
4. Achondroplasia: a comprehensive clinical disease. *Orphanet J Rare Dis*. 2019;14(1):1.
5. Health supervision for people with achondroplasia. American Academy of Pediatrics. *Pediatrics*. 2020;145(6):e20201010.
6. Norditropin® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; July 2025.
7. Skytrofa™ subcutaneous injection [prescribing information]. Princeton, NJ: Ascendis Pharma; September 2025.
8. Sogroya® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; July 2025.

9. Ngenla® subcutaneous injection [prescribing information]. New York, NY: Pfizer; July 2025.
10. Increlex® subcutaneous injection [prescribing information]. Cambridge, MA: Ipsen; July 2025.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy.	7/16/2026	8/15/2026

The policy effective date is in force until updated or retired.