CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Nevada Medicaid

DRUG NAME	Yuviwel (navepegritide)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Yuviwel, initially approved by the FDA in 2026, is a C-type natriuretic peptide (CNP) analog 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).
Achondroplasia is the most common form of skeletal dysplasia with an approximate prevalence of 1 in 20,000 live births. It is an autosomal dominant condition caused by a mutation in the FGFR3 gene which makes the protein that is involved in the development and maintenance of bone and brain tissue.

Yuviwel (navepegritide) will be considered for coverage when the following criteria are met:

Achondroplasia

For **initial** authorization:

1. Member is at least 2 years of age; AND
2. Medication must be prescribed by or in consultation with a pediatric endocrinologist or geneticist; AND
3. Member has a diagnosis of achondroplasia with a FGFR3 gene mutation confirmed by genetic testing; AND
4. Chart notes include radiographic evidence the members epiphyses are open (x-ray results must be included); OR
5. Member has documentation in chart notes showing a tanner stage less than 4; AND
6. Member has documented baseline growth velocity (cm/yr); AND
7. Member has documentation of recent weight in chart notes; AND
8. Member has had a trial and failure of Voxzogo.
9. **Dosage allowed/Quantity limit:** administer by subcutaneous injection once weekly per weight-based dosing (see table below). Quantity limit: 8 kits per 28 days.

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)	
73.6 to 90 kg	8.8 mg	1.6 mL (use 2 kits)	

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes must show an increase in annualized growth velocity (cm/yr); AND
2. Chart notes include radiographic evidence the members epiphyses are open (x-ray results must be included); OR
3. Member has documentation in chart notes showing a tanner stage less than 4; AND
4. Member has documentation of recent weight in chart notes.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Yuviwel (navepegritide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/18/2026	New policy for Yuviwel created.
06/15/2026	Added trial and failure of Voxzogo.

References:

1. Yuviwel [prescribing information]. Ascendis Pharma Growth Disorders A/S; 2026.
2. 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
3. Kubota T, Adachi M, Kitaoka T, et al. Clinical Practice Guidelines for Achondroplasia. *Clin Pediatr Endocrinol*. 2020;29(1):25-42. doi:10.1297/cpe.29.25
4. Cormier-Daire V, AlSayed M, Ben-Omran T, et al. The first European consensus on principles of management for achondroplasia. *Orphanet J Rare Dis.* 2021;16(1):333. Published 2021 Jul 31. doi:10.1186/s13023-021-01971-6
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(3):173-189. doi:10.1038/s41574-021-00595-x

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