UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2358-1
Program	Prior Authorization/Medical Necessity
Medication	Yorvipath® (palopegteriparatide)
P&T Approval Date	12/2024
Effective Date	3/1/2025

1. Background:

Yorvipath® is a parathyroid hormone analog (PTH(1-34)) indicated for the treatment of hypoparathyroidism in adults.

Conventional therapy for hypoparathyroidism consists of active vitamin D (e.g., calcitriol or its analog alfacalcidol) and calcium supplementation.

Limitations of Use:
- Yorvipath was not studied for acute post-surgical hypoparathyroidism.
- Titration scheme was only evaluated in adults who first achieved an albumin-corrected serum calcium of at least 7.8 mg/dL using calcium and active vitamin D treatment.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Yorvipath** will be approved based on **all** of the following criteria:

   a. Diagnosis of hypoparathyroidism

   -AND-

   b. Confirmation of initial diagnosis by **both** of the following:

      (1) Pretreatment low albumin-corrected serum calcium (i.e., ≤ 8.5 mg/dL) confirmed on at least two occasions separated by at least 2 weeks

      -AND-

      (2) Pretreatment undetectable or inappropriately low intact parathyroid (PTH) concentration (i.e., < 20 pg/mL), by second- or third-generation immunoassay, on at least two occasions

   -AND-

   c. Yorvipath is not being used to treat *acute* post-surgical hypoparathyroidism

   -AND-

d. Patient is currently on adequate supplemental calcium and active vitamin D (e.g., calcitriol) therapy as evidenced by **both** of the following:

(1) Albumin-corrected serum calcium 7.8–10.6 mg/dL
(2) Serum 25(OH) vitamin D 20–80 ng/mL

-AND-

e. Prescribed by **one** of the following:

(1) Endocrinologist
(2) Nephrologist

Authorization will be issued for 12 months

B. **Reauthorization**

1. **Yorvipath** will be approved based on **all** of the following criteria:

a. Documentation of positive clinical response [e.g., albumin-corrected serum calcium level in normal range (approximately 8.3-10.6 mg/dL), independence from conventional therapy (e.g., requiring no active vitamin D, ≤ 600 mg/day of calcium)]

-AND-

b. Prescribed by **one** of the following:

(1) Endocrinologist
(2) Nephrologist

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Yorvipath® [package insert]. Princeton, NJ: Ascendis Pharma, Inc.; August 2024.
2. Khan AA, Rejnmark L, Rubin M, et al. PaTH Forward: A Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial of TransCon PTH in Adult Hypoparathyroidism. *J Clin Endocrinol Metab*. 2022;107(1):e372-e385.

3. Khan AA, Rubin MR, Schwarz P, et al. Efficacy and Safety of Parathyroid Hormone Replacement With TransCon PTH in Hypoparathyroidism: 26-Week Results From the Phase 3 PaTHway Trial. J Bone Miner Res. 2023;38(1):14-25.
4. Brandi ML, Bilezikian JP, Shoback D, et al. Management of Hypoparathyroidism: Summary Statement and Guidelines. *J Clin Endocrinol Metab*. 2016;101(6):2273-2283.
5. Clarke BL. Hypoparathyroidism: update of guidelines from the 2022 International Task Force. *Arch Endocrinol Metab*. 2022;66(5):604-610.

Program	Prior Authorization/Medical Necessity - Yorvipath (palopegteriparatide)
Change Control	
12/2024	New program.