Generic Name: Palopegteriparatide

Therapeutic Class or Brand Name: Yorvipath®

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/24/2025

Date Last Reviewed / Revised: 2/24/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of chronic hypoparathyroidism (HP) of postsurgical, autoimmune, genetic, or idiopathic origins, for at least 26 weeks, based on hypocalcemia in the setting of inappropriately low serum PTH levels, and criteria A through D are met:

   A. Currently receiving conventional therapy, including active vitamin D (ie, calcitriol, alfacalcidol, dihydrotachysterol) and elemental calcium.

   B. Patient's disease cannot be adequately controlled on conventional therapy alone (see Appendix Table 1).

   C. Serum 25(OH) vitamin D level of 20–80 ng/mL (49–200 nmol/L) within the past two weeks.

   D. Albumin-corrected serum calcium ≥7.8 mg/dL or ionized serum calcium ≥4.4 mg/dL within the past two weeks.

II. Minimum age requirement of 18 years.

III. Treatment must be prescribed by or in consultation with an endocrinologist or nephrologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Treatment of acute post-surgical hypoparathyroidism.
- Impaired responsiveness to PTH (pseudohypoparathyroidism).
- Diagnosis of any disease that might affect calcium metabolism, calcium-phosphate homeostasis, or PTH levels other than HP.
- Use of osteoporosis therapies known to influence calcium and bone metabolism within the past two years (ie, bisphosphonate).

OTHER CRITERIA

- Click or tap here to enter text.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 2 pen injectors per 28 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing improvement or maintenance with medication as indicated by a recent albumin-corrected serum calcium between 8.3–10.6 mg/dL and documentation that criteria 1 or 2 are met:
  1. Patient no longer requires active vitamin D or therapeutic doses of calcium.
  2. Patient had a significant reduction in required dosages of active vitamin D or calcium and is still actively titrating doses of Yorvipath.

APPENDIX

Table 1. American Society for Bone and Mineral Research (ASBMR) - Examples of Uncontrolled Hypoparathyroidism

Inadequate Control of Hypoparathyroidism
• Symptomatic hypocalcemia
• Hyperphosphatemia
• Renal insufficiency
• Hypercalciuria
• Poor quality of life

REFERENCES

1. Yorvipath. Prescribing Information. Ascendis Pharma Endocrinology, Inc.; 2024. Accessed January 9, 2025.

   https://ascendispharma.us/products/pi/yorvipath/yorvipath_pi.pdf

2. 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. doi:10.1002/jbmr.4726. Accessed January 9, 2025.

   https://pubmed.ncbi.nlm.nih.gov/36271471/

3. Khan AA, Bilezikian JP, Brandi ML, et al. Evaluation and Management of Hypoparathyroidism Summary Statement and Guidelines from the Second International Workshop. J Bone Miner Res. 2022;37(12):2568-2585. doi:10.1002/jbmr.4691. Accessed January 9, 2025.

   https://pubmed.ncbi.nlm.nih.gov/36054621/