Clinical Policy: Palopegteriparatide (Yorvipath)

Reference Number: PA.CP.PHAR.696
Effective Date: 11/2024
Last Review Date: 10/2025

Description
Palopegteriparatide (Yorvipath®) is a parathyroid hormone analog.

FDA Approved Indication(s)
Yorvipath is indicated for the treatment of hypoparathyroidism in adults.

Limitation(s) of use:
- Not studied for acute post-surgical hypoparathyroidism.
- Titration scheme 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Yorvipath is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hypoparathyroidism (must meet all)**:**

1. Diagnosis of hypoparathyroidism;
2. Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years;
4. At therapy initiation, Yorvipath is prescribed as an adjunct to calcium supplements and active forms of vitamin D (e.g., calcitriol), unless contraindicated or clinically significant adverse effects are experienced;
5. Recent (dated within the last 30 days) albumin-corrected serum calcium level is ≥ 7.8 mg/dL;
6. Recent (dated within the last 30 days) lab result shows serum 25-hydroxyvitamin D (25(OH)D) is within the laboratory defined normal range (e.g., 30-100 ng/mL, 75-250 nmol/L);
7. Failure of a 12-week trial of calcium supplements and active forms of vitamin D (e.g., calcitriol) at up to maximally indicated doses, unless contraindicated or clinically significant adverse events are experienced;
   **Prescriber must indicate that the hypocalcemia is not well controlled with calcium supplements and active forms of vitamin D (see examples in Appendix B below).*
8. Dose does not exceed both of the following (a and b):
   a. 30 mcg per day, administered as a single injection;
   b. 2 pend per 28 days.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Hypoparathyroidism (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters:
   a. Albumin-corrected serum calcium in the normal range (e.g., 8.3 to 10.6 mg/dL);
   b. Independence from conventional therapy (e.g., no active vitamin D and elemental calcium supplementation ≤ 600 mg/day);
3. If request is for a dose increase, new dose does not exceed both of the following (a and b).
   a. 30 mcg per day, administered as a single injection;
   b. 2 pens per 28 days.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
calcitriol (Rocaltrol®)	0.25 mcg PO QD initially; dose may be increased at 2- to 4-wk intervals	2 mcg/day

calcium carbonate (Caltrate®, OsCal®, Tums®)	1-3 g PO QD in divided doses	3 g/day
calcium citrate (Cal-Citrate®, Cal-C-Caps®)	1-3 g PO QD in divided doses	3 g/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to any component of the product
- Boxed warning(s): none reported

Appendix D: General Information

- As stated in the prescribing information, the prescriber should confirm 25-hydroxyvitamin D stores are within the normal range and serum calcium is above 7.8 mg/dL before starting Yorvipath.
- The goal of Yorvipath treatment is to maintain serum calcium within the normal range without the need for active vitamin D (e.g., calcitriol) or therapeutic calcium doses (elemental calcium > 600 mg/day).
- Examples of a "failure" of calcium and vitamin D supplementation can include: large swings in calcium levels, calcium phosphate product cannot be maintained within an acceptable range, high risk of renal complications due to hypercalciuria or calcium containing stones, evidence of renal complications such as nephrolithiasis or having a condition causing poor calcium and vitamin D absorption.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hypoparathyroidism	18 mcg SC QD; titrate in 3 mcg increments or decrements with the goal of maintaining serum calcium within the normal range without the need for active vitamin D (e.g., calcitriol) or therapeutic calcium doses (elemental calcium > 600 mg/day)	30 mcg/day

VI. Product Availability

Prefilled, 14-dose pen-injectors: 168 mcg/0.56 mL, 294 mcg/0.98 mL, 420 mcg/1.4 mL

VII. References

1. Yorvipath Prescribing Information. Princeton, NJ: Ascendis Pharma; August 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216490s000lbl.pdf. Accessed July 16, 2025.
2. Rejnmark L, Gosmanova EO, Khan AA, et al. Palopegteriparatide treatment improves renal function in adults with chronic hypoparathyroidism: 1-year results from the phase 3 PaTHway trial. Adv Ther. 2024 Jun;41(6): 2500-2518.
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 Jan;38(1): 14-25.

4. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 17, 2025.
5. Brandi ML, Bilezikian JP, Shoback D, et al. Management of hypoparathyroidism: Summary statement and guidelines. J Clin Endocrinol Metab. June 2016;101(6):2273–83.
6. Khan AA, Bilezikian JP, Brandi ML, et al. Evaluation and management of hypoparathyroidism summary statement and guidelines from the second international workshop. J Bone and Mineral Research. December 2022;37(12):2568-85.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date
Policy created	10/2024
4Q 2025 annual review: extended continued approval duration from 6 to 12 months; references reviewed and updated.	10/2025