Prescribing & Prior Authorization Considerations

Yorvipath®
palopegteriparatide
Injection 300 mcg/mL

This resource is intended to be used as an educational tool to help communicate health plan requirements and may assist in coverage determinations for your patients' YORVIPATH® prescriptions. Coverage criteria can vary depending on the specific health plan. It remains the responsibility of the healthcare professional to determine and define the most appropriate treatment plan for patients with hypoparathyroidism based on individual clinical needs.

INDICATION AND LIMITATIONS OF USE

YORVIPATH® (palopegteriparatide) is indicated for the treatment of hypoparathyroidism in adults.

- YORVIPATH was not studied for acute post-surgical hypoparathyroidism.
- YORVIPATH's 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.

Important Safety Information

CONTRAINDICATIONS

YORVIPATH is contraindicated in patients with a history of severe hypersensitivity to palopegteriparatide or any of the inactive ingredients of YORVIPATH. Reactions have included anaphylaxis, angioedema, and urticaria.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, angioedema, and urticaria have been reported in patients treated with parathyroid hormone (PTH) analogs, including YORVIPATH. If signs or symptoms of a hypersensitivity reaction occur, discontinue treatment with YORVIPATH, initiate appropriate supportive care, and monitor until signs and symptoms resolve. Discontinue YORVIPATH permanently in patients with a severe hypersensitivity reaction to YORVIPATH. YORVIPATH is contraindicated in patients with a history of severe hypersensitivity to palopegteriparatide or any of the inactive ingredients of YORVIPATH.

Risk of Unintended Changes in Serum Calcium Levels Related to Number of Daily Injections

Use only one YORVIPATH injection to achieve the recommended once daily dosage. Using two YORVIPATH injections to achieve the recommended once daily dosage increases the variability of the total delivered dose, which can cause unintended changes in serum calcium levels, including hypercalcemia and hypocalcemia.

Serious Hypercalcemia

Serious events of hypercalcemia requiring hospitalization have been reported with YORVIPATH. The risk is highest when starting or increasing the dose of YORVIPATH but may occur at any time. Measure serum calcium 7 to 10 days after any dose change or if there are signs or symptoms of hypercalcemia, and at a minimum of every 4 to 6 weeks once the maintenance dose is achieved. Treat hypercalcemia if needed. If albumin-corrected serum calcium is greater than 12 mg/dL, withhold YORVIPATH for at least 2-3 days. For less serious hypercalcemia, adjust the dose of YORVIPATH, active vitamin D, and/or calcium supplements.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for YORVIPATH.

Navigating YORVIPATH® Prescribing and Dosing[1]

Dosing

The recommended starting pen for YORVIPATH is **294 mcg/0.98 mL** as it corresponds with the recommended starting dose of **18 mcg** once daily

Prescribing YORVIPATH

When prescribing a **28-day supply** of YORVIPATH for your patient, each carton will include:

- 2 individually packaged prefilled pens
- 28 needles, plus 2 spare needles

An ePA or eRx platform may ask you to select either the prefilled pen presentation or the medication by its NDC number. To ensure accuracy, refer to the patient's administered dose when selecting the correct presentation.

YORVIPATH pen volumes, corresponding doses, and package information

	Prefilled Pen Presentation	Labeled Doses	mL Quantity	NDC
	**YORVIPATH (168 mcg/0.56 mL)** blue pen	6, 9, and 12 mcg	1.12 mL	73362-100-01
RECOMMENDED STARTING DOSE 	**YORVIPATH (294 mcg/0.98 mL)** orange pen	15, 18, and 21 mcg	1.96 mL	73362-101-01
	**YORVIPATH (420 mcg/1.4 mL)** burgundy pen	24, 27, and 30 mcg	2.8 mL	73362-102-01

ePA=electronic prior authorization; eRX=electronic prescription; NDC=National Drug Code.

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Serious Hypocalcemia

Serious events of hypocalcemia have been observed with PTH products, including YORVIPATH. The risk is highest when YORVIPATH is abruptly discontinued, but may occur at any time, even in patients who have been on stable doses of YORVIPATH. Measure serum calcium 7 to 10 days after any dose change or if there are signs or symptoms of hypocalcemia, and at a minimum of every 4 to 6 weeks once the maintenance dosage is achieved. Treat hypocalcemia if needed, and adjust the dose of YORVIPATH, active vitamin D, and/or calcium supplements if hypocalcemia occurs.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for YORVIPATH.

Yorvipath®
palopegteriparatide
Injection 300 mcg/mL

Prior Authorization (PA) Considerations

The checklist below highlights items and information that may be required before coverage for YORVIPATH® is approved.

This checklist is for informational purposes only and cannot guarantee that coverage will be granted. Specific documentation may vary between health plans, so it is important to review the individual guidelines for each health plan, as a specific PA form may be required.

PATIENT CLINICAL DOCUMENTATION:

Diagnosis

- ☐ Summary of patient's diagnosis
- ☐ Diagnosis code (ICD-10-CM)*[2]
  - ✓ E20: Hypoparathyroidism
  - ✓ E20.0: Idiopathic hypoparathyroidism
  - ✓ E20.8: Other hypoparathyroidism
  - ✓ E20.9: Hypoparathyroidism, unspecified
  - ✓ E89.2: Postprocedural hypoparathyroidism
  - ✓ D82.1: Di George's syndrome

Treatment History

- ☐ Procedure(s) or treatment history
  - ✓ Date(s) of surgery (for E89.2 only)
  - ✓ Duration of treatment
  - ✓ Adverse events
  - ✓ Outcomes

Conventional Therapy[5,6]

- ☐ Dosage of active vitamin D, calcium, magnesium supplements, thiazide diuretics, phosphate binders

Lab Results (from the last 30 days)

- ☐ Confirm the following are within normal laboratory limits:
  - ✓ Albumin-corrected serum calcium ≥7.8 mg/dL
    - Albumin
    - Serum calcium
  - ✓ Serum 25(OH) vitamin D
  - ✓ Magnesium levels

Clinical Details

- ☐ Surgeries
  - ✓ If patient has post-surgical hypoparathyroidism and it has been ≥6 months, they have chronic hypoparathyroidism[3,4]
  - ✗ YORVIPATH is not indicated for **acute** post-surgical hypoparathyroidism[1]
- ☐ Hospitalizations
- ☐ Symptoms[5-7]
  - ✓ Nephrolithiasis, nephrocalcinosis, and/or Chronic kidney disease
  - ✓ Muscle pain, cramping, tetany, or paresthesia

*ICD-10-CM codes typically associated with PTH. For informational purposes only. It is the responsibility of the healthcare provider to determine the appropriate diagnosis code(s) for his/her patient.

ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification.

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Potential Risk of Osteosarcoma

YORVIPATH is a PTH analog. An increased incidence of osteosarcoma (a malignant bone tumor) has been reported in male and female rats treated with PTH analogs, including teriparatide. Osteosarcoma occurrence in rats is dependent on teriparatide or PTH dose and treatment duration. Osteosarcoma has been reported in patients treated with teriparatide in the postmarketing setting; however, an increased risk of osteosarcoma has not been observed in observational studies in humans. There are limited data assessing the risk of osteosarcoma beyond 2 years of teriparatide use.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for YORVIPATH.

Yorvipath®
palopegteriparatide
Injection 300 mcg/mL

Importance of Laboratory Testing

Health plans use the prior authorization (PA) process to ensure YORVIPATH® is prescribed according to its approved FDA label, which relies heavily on lab values. Laboratory testing is critical for prescribing and titrating YORVIPATH, as it plays a critical role in ensuring the medication is used safely and effectively.[1]

Reauthorizations often require updated labs.

Serum albumin-corrected calcium is between 7.8 and 10.6 mg/dL[8]

YORVIPATH titration is based on serum calcium levels. For a serum albumin-corrected calcium test, the lab will do the following[1]:

YORVIPATH Prescribing Information states that albumin-corrected serum calcium must be ≥7.8 at the initiation of YORVIPATH.

- Blood draw: Test requires a blood sample, which is typically obtained through a venipuncture (standard blood draw procedure).
- Albumin measurement: To correct calcium levels for albumin, both serum calcium and albumin levels need to be measured. This means that two tests are essentially performed from the same blood sample.
- Calculation: The correction formula is applied to the results, which can be done manually or automatically by the lab's software.

25-hydroxyvitamin D is between 20 and 80 ng/mL[8]

- Blood draw: Obtaining a vitamin D level is generally straightforward and involves a simple blood test. The test measures the level of 25 hydroxyvitamin D (25(OH)D) in the blood, which is the most accurate indicator of vitamin D status.

Serum magnesium concentration is greater than or equal to 1.3 mg/dL and below the upper limit of normal of the reference range[8]

Within 2 weeks before the first dose of YORVIPATH, confirm serum 25(OH) vitamin D is within the normal range and albumin-corrected serum calcium is ≥7.8 mg/dL. Your patient's Specialty Pharmacy may call to confirm lab values.[1]

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Potential Risk of Osteosarcoma (cont'd)

YORVIPATH is not recommended in patients who are at increased risk of osteosarcoma, such as patients with:

- Open epiphyses. YORVIPATH is not approved in pediatric patients.
- Metabolic bone diseases other than hypoparathyroidism, including Paget's disease of bone.
- Unexplained elevations of alkaline phosphatase.
- Bone metastases or a history of skeletal malignancies.
- History of external beam or implant radiation therapy involving the skeleton.
- Hereditary disorders predisposing to osteosarcoma.

Instruct patients to promptly report clinical symptoms (e.g., persistent localized pain) and signs (e.g., soft tissue mass tender to palpation) that could be consistent with osteosarcoma.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for YORVIPATH.

Yorvipath®
palopegteriparatide
Injection 300 mcg/mL

Make Sure Your Request is Complete

- ✓ All patient information is consistent and correctly entered
- ✓ Appropriate patient records are attached
- ✓ Prior hospitalizations are noted (if the clinical rationale above is evidenced by a hospitalization)
- ✓ Prescribing Information and Important Safety Information for YORVIPATH® are attached
- ✓ Provider completes and signs form
- ✓ **Send the enrollment form to A·S·A·P**

Ascendis is partnered with Orsini Specialty Pharmacy and PANTHERx Rare Pharmacy for YORVIPATH dispensing.

Orsini Specialty Pharmacy	Phone: (888) 204-7802	Fax: (877) 471-8175	orsinispecialtypharmacy.com
PANTHERx Rare Pharmacy	Phone: (888) 379-1821	Fax: (877) 914-0604	pantherxrare.com

The Ascendis Signature Access Program® (A·S·A·P)

A·S·A·P can provide support for your patients throughout treatment and answer any questions your office may have. Through A·S·A·P, a **Field Reimbursement Manager (FRM)** can work closely with your office to:

A·S·A·P
ASCENDIS SIGNATURE ACCESS PROGRAM®

- Identify missing information on the completed Enrollment Form
- Ensure your office understands requirements for a PA or medical exception submission
- Confirm understanding of the benefits investigation
- Advise on the resubmission and appeal process

Please click here to visit the A·S·A·P website where you can access additional helpful resources or call to speak with an **FRM** at **1-844-442-7236** (8 AM to 8 PM, Mon - Fri)

Yorvipath®
palopegteriparatide
Injection 300 mcg/mL

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Orthostatic Hypotension

Orthostatic hypotension has been reported with YORVIPATH®. Associated signs and symptoms may include decreased blood pressure, dizziness (including postural dizziness), palpitations, tachycardia, presyncope, or syncope. Such symptoms can be managed by dosing at bedtime, while reclining. YORVIPATH should be administered initially when the patient can sit or lie down due to the potential of orthostatic hypotension.

Risk of Digoxin Toxicity With Concomitant Use of Digitalis Compounds

YORVIPATH increases serum calcium, and therefore, concomitant use with digoxin (which has a narrow therapeutic index) may predispose patients to digitalis toxicity if hypercalcemia develops. Digoxin efficacy may be reduced if hypocalcemia is present. When YORVIPATH is used concomitantly with digoxin, measure serum calcium and digoxin levels routinely, and monitor for signs and symptoms of digoxin toxicity. Refer to the digoxin prescribing information for dose adjustments, if needed.

ADVERSE REACTIONS

The most common adverse reactions (≥ 5%) in patients treated with YORVIPATH and with ≥2% higher frequency compared to placebo were injection site reactions (39%), vasodilatory signs and symptoms (28%), headache (21%), diarrhea (10%), back pain (8%), hypercalcemia (8%) and oropharyngeal pain (7%).

DRUG INTERACTIONS

Drugs Affected by Serum Calcium

Digoxin: YORVIPATH increases serum calcium, therefore, concomitant use with digoxin (which has a narrow therapeutic index) may predispose patients to digitalis toxicity if hypercalcemia develops. Digoxin efficacy may be reduced if hypocalcemia is present. When YORVIPATH is used concomitantly with digoxin, measure serum calcium and digoxin levels, and monitor for signs and symptoms of digoxin toxicity. Adjustment of the digoxin and/or YORVIPATH dose may be needed.

Drugs Known to Affect Serum Calcium

Drugs that affect serum calcium may alter the therapeutic response to YORVIPATH. Measure serum calcium more frequently when YORVIPATH is used concomitantly with these drugs, particularly after these drugs are initiated, discontinued, or dose adjusted.

USE IN SPECIFIC POPULATIONS

Pregnancy

Available data from reports of pregnancies in the clinical trials from drug development are insufficient to identify a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. If YORVIPATH is administered during pregnancy, or if a patient becomes pregnant while receiving YORVIPATH, healthcare providers should report YORVIPATH exposure by calling 1-877-229-2184.

Lactation

Monitor infants breastfed by females treated with YORVIPATH for symptoms of hypercalcemia or hypocalcemia. Consider monitoring serum calcium in the breastfed infant

You are encouraged to report side effects to FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Ascendis Pharma at 1-844-442-7236.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for YORVIPATH.

References: 1. YORVIPATH. Prescribing information. Ascendis Pharma; 2026. **2.** 2026 ICD-10-CM Diagnosis Code E2-. ICD10Data.com. Accessed April 8, 2026. https://www.icd10data.com/ICD10CM/Codes/E00-E89/E20-E35/E20-. **3.** Clark BL. Hypoparathyroidism: update of guidelines from the 2022 International Task Force. *Arch Endocrinol Metab*. 2022;66(5):604-610. doi: 10.20945/2359-3997000000549. **4.** Brandi M, Bilezikian JP, Shoback D, et al. Management of Hypoparathyroidism: Summary Statement and Guidelines. *J Clin Endocrinol Metab*. 2016;101(6):2273-2283. doi: 10.1210/jc.2015-3907. Epub 2016 Mar 4. **5.** Rubin MR. Recent Advances in understanding and managing hypoparathyroidism. *F1000Res*. 2020;9(Faculty Rev):766. doi: 10.12688/f1000research.22717.1. **6.** Khan AA, Guyatt G, Ali DS, et al. Management of Hypoparathyroidism. *J Bone Miner Res*. 2022;37(12):2663-2667. doi: 10.1002/jbmr.4716. **7.** Hadker N, Egan J, Sanders J, et al. Understanding the burden of illness associated with hypoparathyroidism reported among patients in the PARADOX study. *Endocr Pract*. 2014;20(7):671-679. doi: 10.4158/EP13328.OR.2022;37(12):2568-2585. **8.** Khan AA, Rubiin 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.

ascendis pharma

© August 2026 Ascendis Pharma Endocrinology, Inc. All rights reserved.
YORVIPATH®, the YORVIPATH® logo, Ascendis Signature Access Program®, Ascendis®, the Ascendis Pharma logo and the company logo are trademarks owned by the Ascendis Pharma Group.
US-COMMPTH-2600317 08/26

Yorvipath®
palopegteriparatide
Injection 300 mcg/mL