Yorvipath®
palopegteriparatide
Injection 300 mcg/mL

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.

Prescribing Considerations

This document provides the general information commonly requested by health plans. This information may change depending on the health plan, and it is the responsibility of the healthcare professional to best define the treatment plan for their patient with hypoparathyroidism.

YORVIPATH (palopegteriparatide) Important Safety Information

INDICATION AND LIMITATION OF USE

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Important Safety Information (cont'd)

CONTRAINDICATIONS

YORVIPATH is contraindicated in patients with severe hypersensitivity to palopegteriparatide or to any of its excipients. Hypersensitivity reactions, including anaphylaxis, angioedema, and urticaria, have been observed with parathyroid hormone (PTH) analogs.

WARNINGS AND PRECAUTIONS

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.

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

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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

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To expedite a coverage determination for YORVIPATH®, please include the information below in your initial request for coverage.

1 Diagnosis

- Age/diagnosis: treatment of adults (aged 18 years or older) with hypoparathyroidism
- Is prescribed by or in consultation with an endocrinologist (some health plans may allow for prescribing by or in consultation with a nephrologist and/or other specialist as well)

ICD-10-CM Diagnosis Codes[2]

For informational purposes only. It is the responsibility of the healthcare provider to determine the appropriate diagnosis code(s) for his or her patient

- **E20:** Hypoparathyroidism
- **E20.0:** Idiopathic hypoparathyroidism
- **E20.8:** Other hypoparathyroidism
- **E20.9:** Hypoparathyroidism, unspecified
- **E89.2:** Postprocedural hypoparathyroidism
- **D82.1:** Di George's syndrome

2 Treatment History and Lab Values Specific to Diagnosis

(prescriber attestation or documentation if needed)

- Date of thyroid or anterior neck surgery (if applicable)
- Medication (prescription, over the counter and/or supplement treatment) name
  - Dosage
  - Starting date, duration, and outcome of treatments
- Albumin-corrected serum calcium ≥7.8 mg/dL[1]

3 Clinical Rationale for Prescribing YORVIPATH[3]

(prescriber attestation or documentation if needed)

- Inadequate control with conventional management
- Poor compliance, malabsorption
- Intolerance to large doses of calcium and active vitamin D
- Risk of nephrolithiasis, nephrocalcinosis, or renal insufficiency

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.

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.

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

How A·S·A·P supports patients.

The A·S·A·P program provides patient support services to eligible patients who were prescribed YORVIPATH for its approved indication. For personalized support and to learn more, call **1-844-442-7236** (available from **8AM - 8PM ET, Monday through Friday**).

Make Sure Your Request is Complete

- ✓ All patient information is consistent and correctly entered
- ✓ Appropriate patient records are attached (if requested)
- ✓ 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

Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (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.

PTH = parathyroid hormone.

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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 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 1-844-442-7236.

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 click here for full Prescribing Information for YORVIPATH.

References: 1. YORVIPATH. Prescribing information. Ascendis Pharma; 2024. **2.** 2025 ICD-10-CM Diagnosis Code E20-. ICD10Data.com. Accessed December 16, 2024. https://www.icd10data.com/ICD10CM/Codes/E00-E89/E20-E35/E20- **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.

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