

Specialty Guideline Management Yorvipath

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Yorvipath	palopegteriparatide

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Yorvipath is indicated for the treatment of hypoparathyroidism in adults.

Limitations of Use

- 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 milligrams per deciliter (mg/dL) using calcium and active vitamin D treatment.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Yorvipath SGM 6588-A P2025.docx

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Reference number(s)
6588-A

Initial requests

- Lab results confirming serum 25-hydroxyvitamin D concentration is above the lower limit of normal laboratory range.
- Lab results confirming albumin-corrected serum calcium is greater than or equal to 7.8 mg/dL prior to initiating therapy with the requested medication.
- Chart notes, medical record documentation, or claims history supporting current use of calcium supplementation and active vitamin D therapy, including response to therapy.
- Lab results confirming serum magnesium level is within normal laboratory limits.

Continuation requests

- Lab results confirming maintenance or normalization of albumin-corrected calcium levels compared to baseline.
- Chart notes, medical record documentation, or claims history showing beneficial response to therapy.

Exclusions

Coverage will not be provided for members with acute post-surgical hypoparathyroidism (within 6 months of surgery) and expected recovery from hypoparathyroidism.

Prescriber Specialties

This medication must be prescribed by or in consultation with an endocrinologist, nephrologist, or a physician specializing in the treatment of metabolic bone disorders.

Coverage Criteria

Hypoparathyroidism¹⁻³

Authorization of 12 months may be granted for treatment of hypoparathyroidism in adult members when all of the following criteria are met:

- Member has had hypoparathyroidism for six months or more.
- Serum 25-hydroxyvitamin D concentration is above the lower limit of normal laboratory range.
- Albumin-corrected serum calcium level is greater than or equal to 7.8 mg/dL prior to initiating therapy with the requested medication.

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- Member has an inadequate response to maximally tolerated calcium supplementation and active vitamin D therapy (e.g., calcitriol, alfacalcidol).
- Member will continue calcium supplementation and active vitamin D therapy while titrating to an appropriate dose of the requested medication.
- Serum magnesium level is within normal laboratory limits.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in adult members requesting reauthorization for an indication listed in the coverage criteria and meets both of the following criteria:

- Maintenance or normalization of albumin-corrected calcium levels from baseline.
- Member is experiencing benefit from therapy (e.g., reduction in calcium supplementation or active vitamin D therapy dose from baseline, independence from calcium supplementation or active vitamin D therapy).

References

1. Yorvipath [package insert]. Princeton, NJ: Ascendis Pharma Endocrinology, Inc.; August 2024.
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.
3. Khan AA, Ali DS, Bilezikian JP, et al. Best practice recommendations for the diagnosis and management of hypoparathyroidism. *Metabolism.* 2025;171:156335. doi: 10.1016/j.metabol.2025.156335