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Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	August 30, 2024
Subject:	Yorvipath	**Page:**	1 of 4

Last Review Date: September 19, 2025

Yorvipath

Description

Yorvipath (palopegterlparatide)

Background
Yorvipath (palopegterlparatide) releases parathyroid hormone (PTH) (1-34) to maintain a continuous systemic exposure. Endogenous PTH maintains extracellular calcium and phosphate homeostasis by increasing serum calcium and decreasing serum phosphate. These effects are mediated by stimulating bone turnover to mobilize calcium and phosphate from bone, promoting renal calcium reabsorption and phosphate excretion, and facilitating active vitamin D synthesis, in turn increasing intestinal absorption of calcium and phosphate. Similar to endogenous PTH, PTH (1-34) released from Yorvipath exerts these effects through its main receptor, parathyroid hormone 1 receptor (PTH1R), which is highly expressed on osteoblasts, osteocytes, renal tubular cells, and in several other tissues (1).

Regulatory Status
FDA-approved indication: Yorvipath is a parathyroid hormone analog (PTH (1-34)) indicated for the treatment of hypoparathyroidism in adults (1).

Limitations of Use: (1)

1. Not studied for acute post-surgical hypoparathyroidism.
2. 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.

Yorvipath carries warnings for changes in serum calcium levels, serious hypercalcemia and hypocalcemia, risk of osteosarcoma, orthostatic hypotension, and digoxin toxicity. Using more than one injection to achieve the recommended daily dose can increase the variability of the total delivered dose, which can cause unintended changes in serum calcium. Therefore, use one injection to achieve the recommended once daily dose. Serum calcium should be measured 7 to 10 days after any change in dose or if signs and symptoms of hypercalcemia or hypocalcemia are present. Once maintenance dosage is achieved, serum calcium levels should be measured every 4 to 6 weeks. Yorvipath is not recommended in patients at risk for osteosarcoma. Yorvipath should be administered when the patient can sit or lie down due to the potential of orthostatic hypotension. Since Yorvipath increases serum calcium, concomitant digoxin use may predispose patients to digitalis toxicity if hypercalcemia develops. Serum calcium and digoxin levels should be measured routinely, and dosing should be adjusted if needed (1).

The safety and effectiveness of Yorvipath in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Yorvipath may be considered **medically necessary** if the conditions indicated below are met.

Yorvipath may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Hypoparathyroidism

AND ALL of the following:

1. Inadequate treatment response, intolerance, or contraindication to conventional therapy (e.g., oral calcium and/or calcitriol)
2. Albumin-corrected serum calcium ≥7.8 mg/dL prior to initiation of therapy
3. Serum 25-hydroxyvitamin D level is within the normal range prior to initiation of therapy
4. **NO** acute post-surgical hypoparathyroidism (within 6 months of surgery)
5. Prescriber agrees to monitor for hypercalcemia and hypocalcemia
6. One injection will be used to achieve the once daily recommended dosage

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Hypoparathyroidism

AND ALL of the following:

1. Prescriber agrees to monitor for hypercalcemia and hypocalcemia
2. One injection will be used to achieve the once daily recommended dosage

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 6 prefilled pens* per 84 days

*Each prefilled pen contains 14 doses

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Yorvipath is a parathyroid hormone analog (PTH (1-34)) indicated for the treatment of hypoparathyroidism. Yorvipath carries warnings for changes in serum calcium levels, serious hypercalcemia and hypocalcemia, risk of osteosarcoma, orthostatic hypotension, and digoxin toxicity. The safety and effectiveness of Yorvipath in pediatric patients less than 18 years of age has not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Yorvipath while maintaining optimal therapeutic outcomes.

References

1. Yorvipath [package insert]. Hellerup, Denmark: Ascendis Pharma Bone Diseases A/S; August 2024.

Policy History

Date	Action
August 2024	Addition to PA
December 2024	Annual review. Per SME, added “and/or” to t/f oral calcium or calcitriol requirement
September 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.