

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Yorvipath (palopegteriparatide)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Yorvipath, approved by the FDA in 2024, is a parathyroid hormone analog (PTH(1-34)) indicated for the treatment of hypoparathyroidism in adults. It has not been studied for acute post-surgical hypoparathyroidism, and should not be used in those with increased risk of osteosarcoma. It is the prodrug of teriparatide, and is identical to the biologically active region of the 84-amino acid human PTH.

Hypoparathyroidism is an endocrine disease caused by insufficient or absent production of parathyroid hormone (PTH) leading to hypocalcemia and hyperphosphatemia. Multiple organ systems are affected, including neuromuscular, cardiovascular, and renal dysfunction.

Conventional therapy is calcium and active forms of vitamin D to resolve hypocalcemia, but this does not restore normal PTH. Endogenous PTH maintains extracellular calcium and phosphate homeostasis by increasing serum calcium and decreasing serum phosphate.

Yorvipath (palopegteriparatide) will be considered for coverage when the following criteria are met:

Hypoparathyroidism

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has a diagnosis of hypoparathyroidism for at least 26 weeks based on labs that show both of the following:
 - a) Hypocalcemia, and
 - b) Low serum PTH; AND
4. Member is uncontrolled on conventional therapy with optimized calcium AND active vitamin D (e.g., calcitriol); AND
5. Member's current albumin-corrected serum calcium is at least 7.8 mg/dL.
6. **Dosage allowed/Quantity limit:** Administer as a single subQ injection. Start at 18 mcg once daily. Titrate per prescribing information, based on serum calcium levels. Max dose 30 mcg once daily. QL: 2 pens per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show a positive clinical response such as normalized calcium levels, reduced need for conventional therapy, and improved quality of life.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Yorvipath (palopegteriparatide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/23/2024	New policy for Yorvipath created.

References:

1. Yorvipath [prescribing information]. Ascendis Pharma Bone Diseases A/S; 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. doi:10.1002/jbmr.4726
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. doi:10.1002/jbmr.4691

Effective date: 04/01/2025

Revised date: 09/23/2024