Yorvipath® (palopegteriparatide)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
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 mg/dL using calcium and active vitamin D treatment

POLICY

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

1. For initial requests:
    a. Chart notes, medical record documentation, or claims history supporting current use of vitamin D metabolite/analog therapy and elemental calcium
    b. Lab results confirming serum 25-hydroxyvitamin D concentration is above the lower limit of normal laboratory range
    c. 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
    d. Lab results confirming serum magnesium level is within normal laboratory limits
2. For continuation requests:

a. Lab results confirming maintenance or normalization of calcium levels compared to baseline
b. Chart notes, medical record documentation, or claims history supporting discontinuation or significant reduction in required dosages of vitamin D metabolite/analog therapy and therapeutic doses of elemental calcium

Exclusions

Coverage will not be provided for members with the following exclusion:
Acute postsurgical hypoparathyroidism (within 6 months of surgery) and expected recovery from hypoparathyroidism.

Prescriber Specialties

The requested medication must be prescribed by or in consultation with an endocrinologist, nephrologist, or physician specializing in the treatment of metabolic bone disease.

Criteria for Initial Approval

Hypoparathyroidism

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

1. Member has a confirmed diagnosis of chronic hypoparathyroidism for at least 6 months based on hypocalcemia in the setting of inappropriately low serum parathyroid hormone levels
2. Member cannot be adequately controlled on conventional therapy alone
3. Member has an inadequate response to maximally tolerated calcium supplementation and active vitamin D therapy (e.g., calcitriol, alfacalcidol).
4. Member will continue calcium supplementation and active vitamin D therapy while titrating to an appropriate dose of the requested medication.
5. Recent serum 25-hydroxyvitamin D concentration is above the lower limit of normal laboratory range
6. Recent albumin-corrected serum calcium level is greater than or equal to 7.8 mg/dL prior to initiating therapy with the requested medication
7. Recent serum magnesium level is within normal laboratory limits

Continuation of Therapy

Hypoparathyroidism

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

1. Member is experiencing benefit from therapy as evidenced by maintenance or normalization of albumin-corrected serum calcium levels compared to baseline.
2. One of the following are met:
    A. Member no longer requires active vitamin D or therapeutic doses of elemental calcium (≥600 mg per day)
    B. Member has had a significant reduction in the required dosages of active vitamin D and elemental calcium and is still actively titrating doses of the requested medication

Other

Yorvipath (palopegteriparatide) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Yorvipath (palopegteriparatide) 168 mcg/0.56 mL prefilled pen injector	2 pens per 28 days	Initial dosage of 18 mcg subcutaneously once daily. Titrate in 3 mcg increments or decrements with the goal of maintaining serum calcium within the normal range without the need for active vitamin D or therapeutic calcium doses (elemental calcium >600 mg/day). Maximum recommended dosage is 30 mcg subcutaneously once daily. Use only one injection to achieve the once daily recommended dosage.
Yorvipath (palopegteriparatide) 294 mcg/0.98 mL prefilled pen injector		
Yorvipath (palopegteriparatide) 420 mcg/1.4 mL prefilled pen injector		

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

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

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.

POLICY HISTORY

Policy #: 05.05.61

Original Effective Date: December 13, 2024

Reviewed: January 2026

Revised: January 2026

Current Effective Date: March 10, 2026