BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

YORVIPATH® (palopegteriparatide) Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Yorvipath (palopegteriparatide) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist

2. Individual is 18 years of age or older

3. Individual has a confirmed diagnosis of **hypoparathyroidism** that is not controlled with use of calcium supplements and active forms of vitamin D

4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
    a. 25-hydroxyvitamin D is between 20 and 80 ng/mL
    b. Serum albumin-corrected calcium is between 7.8 and 10.6 mg/dL
    c. Serum magnesium concentration is greater than or equal to 1.3 mg/dL and below the upper limit of normal of the reference range
    d. 24-hour urinary calcium

6. Yorvipath (palopegteriparatide) is **not** being used in an individual with acute post-surgical hypoparathyroidism

7. Individual does **not** have risk factors for osteosarcoma (see Definitions section)

8. There is no evidence of hypocalcemia or hypercalcemia

9. Yorvipath (palopegteriparatide) is **not** being used concurrently with teriparatide (generic or brand Forteo), or Tymlos (abaloparatide), Prolia (denosumab) or Xgeva (denosumab)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Yorvipath (palopegteriparatide) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist

2. Individual's condition has responded while on therapy with response defined as the following:
    a. Achieves and maintains **TWO** of the following:
        i. Total serum calcium (albumin-corrected) is within the lower half of the normal range (i.e., between 8.3-10.6 mg/dL) without the need for active forms of vitamin D (ex., calcitriol) or therapeutic calcium doses (ex., elemental calcium greater than 600 mg per day). Calcium supplementation sufficient to meet the individual's daily dietary requirements may be continued
        ii. At least a 50% reduction from baseline in the dose of active vitamin D
        iii. At least a 50% reduction from baseline in the dose of therapeutic oral calcium supplementation
    b. No evidence of disease progression

3. Individual has been adherent with the medication

4. Requested dose is not greater than 30 mcg once daily given as one injection

5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual does **not** have risk factors for osteosarcoma (see Definitions section)

7. There is no evidence of hypocalcemia or hypercalcemia

8. Yorvipath (palopegteriparatide) is **not** being used concurrently with teriparatide (generic or brand Forteo), or Tymlos (abaloparatide), Prolia (denosumab) or Xgeva (denosumab)

9. Individual has not developed any significant unacceptable adverse drug effects that may exclude continued use such as:
    a. Severe hypercalcemia
    b. Severe hypocalcemia
    c. Hypercalciuria (urine calcium > 300mg/24 hours or > 7.5 mmol/24 hours)
    d. Osteosarcoma

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Yorvipath (palopegteriparatide) 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. The titration dosing 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. The normal range for albumin-corrected serum calcium is 8.3 to 10.6 mg/dL. Palopegteriparatide is a prodrug of teriparatide (PTH (1-34)) consisting of PTH (1-34) transiently conjugated to an inert carrier via a proprietary TransCon Linker. The carrier is a methoxypolyethylene glycol (mPEG) moiety.

The maximum dose of Yorvipath (palopegteriparatide) is 30 mcg subcutaneously once daily using once injection. Use of two injections to achieve a once daily dosage increases the variability of the total delivered dose which may lead to hypocalcemia or hypercalcemia. Individualize dosage based on serum calcium.

Parathyroid hormone raises serum calcium by increasing renal tubular calcium reabsorption, increasing intestinal calcium absorption (by converting 25-OH vitamin D to 1, 25-OH2 vitamin D) and by increasing bone turnover which releases calcium into the circulation.

PHARMACY COVERAGE GUIDELINE

YORVIPATH® (palopegteriparatide) Generic Equivalent (if available)

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Adult: Age 18 years and older

Increased risk of osteosarcoma patients with:

- Open epiphyses
- Metabolic bone diseases including Paget's disease or unexplained elevations of alkaline phosphatase
- Bone metastases or history of skeletal malignancies
- Prior external beam or implant radiation therapy involving the skeleton
- Hereditary disorders predisposing to osteosarcoma.

Albumin-corrected serum calcium [cCa, mg/dL]:

Individual's serum calcium (mg/dL) + 0.8 (4.0 – individual's serum albumin [g/dL])

25 hydroxy-vitamin D levels:

20-50 ng/mL (50-125 nmol/L)

Resources:

Yorvipath (palopegteriparatide) product information, revised by Ascendis Pharma, Inc. 08-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 04, 2024.

Glotzman D. Hypoparathyroidism. In: UpToDate, Rosen CJ, Wolfsdorf JI, Mulder JE (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through September 2024. Topic last updated August 24, 2024. Accessed October 14, 2024.

Glotzman D. Treatment of hypocalcemia. In: UpToDate, Rosen CJ, Mulder JE (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through March 2024. Topic last updated March 08, 2023. Accessed April 24, 2024.

Dawson-Hughes B. Vitamin D deficiency in adults: Definition, clinical manifestations, and treatment. In: UpToDate, Rosen CJ, Rubinow K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through March 2024. Topic last updated September 30, 2024. Accessed April 24, 2024.

Mannstadt M. Parathyroid hormone secretion and action. In: UpToDate, Rosen CJ, Rubinow K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through March 2024. Topic last updated March 24, 2023. Accessed April 24, 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 Jan; 38(1): 14–25.

ORIGINAL EFFECTIVE DATE: 11/21/2024 | ARCHIVE DATE: | LAST REVIEW DATE: | LAST CRITERIA REVISION DATE: