Effective Date: 05/2025
Reviewed: 02/2025
Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

YORVIPATH (palopegteriparatide)

POLICY

I. 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 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

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

II. 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.

III. CRITERIA FOR INITIAL APPROVAL

Hypoparathyroidism
Authorization of 6 months may be granted for treatment of hypoparathyroidism in adult members when all of the following criteria are met:

A. Documentation that member has a diagnosis of chronic hypoparathyroidism of postsurgical, autoimmune, genetic, or idiopathic origins, for at least 26 weeks.
B. Member is ≥18 years of age.
C. Yorvipath is prescribed by, or in consultation with, an endocrinologist.
D. Documentation that member is receiving vitamin D metabolite/analog therapy with calcitriol greater than or equal to 0.5 mcg per day.
E. Documentation that member is receiving elemental calcium treatment greater than or equal to 800 mg per day.
F. Documentation that serum 25-hydroxyvitamin D concentration is above the lower limit of normal laboratory range.
G. Documentation that albumin-corrected serum calcium level is greater than or equal to 7.8 mg/dL prior to initiating therapy with the requested medication.
H. Documentation that serum magnesium level is within normal laboratory limits.

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in adult members requesting reauthorization for an indication listed in Section III and who are experiencing benefit from therapy as evidenced by documentation that confirms maintenance or normalization of calcium levels compared to baseline, and one of the following:

- Member no longer requires active vitamin D supplementation and requires ≤600 mg/day of calcium supplementation; OR

- Member has had a reduction in required doses of vitamin D and calcium supplementation and is still actively titrating Yorvipath dose
    - Note: if member is receiving a maximum tolerated dose of Yorvipath which does not result in normocalcemia AND independence from active vitamin D and therapeutic dose of calcium then approval will not be granted.

V. QUANTITY LIMIT

Yorvipath injection 168 mg/0.56 mL: 2 pen injectors (1.12 mL) per 28 days (daily dose of 0.04 mL)
Yorvipath injection 294 mg/0.98 mL: 2 pen injectors (1.96 mL) per 28 day (daily dose of 0.07 mL)
Yorvipath injection 420 mg/1.4 mL: 2 pen injectors (2.8 mL) per 28 days (daily dose of 0.1 mL)

VI. REFERENCES

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