Reference number(s)
6588-A

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. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. For initial requests:
   1. Chart notes, medical record documentation, or claims history supporting current use of vitamin D metabolite/analog therapy and elemental calcium
   2. Lab results confirming serum 25-hydroxyvitamin D concentration is above the lower limit of normal laboratory range
   3. 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
   4. Lab results confirming serum magnesium level is within normal laboratory limits
B. For continuation requests: Lab results confirming maintenance or normalization of calcium levels compared to baseline

III. 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.

IV. CRITERIA FOR INITIAL APPROVAL

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

A. Member has hypoparathyroidism for six months or more.
B. Member is receiving vitamin D metabolite/analog therapy with calcitriol greater than or equal to 0.5 mcg per day or alfacalcidol greater than or equal to 1.0 mcg per day.
C. Member is receiving elemental calcium treatment greater than or equal to 800 mg per day.
D. Serum 25-hydroxyvitamin D concentration is above the lower limit of normal laboratory range.
E. Albumin-corrected serum calcium level is greater than or equal to 7.8 mg/dL prior to initiating therapy with the requested medication.
F. Serum magnesium level is within normal laboratory limits.

V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in adult members requesting reauthorization for an indication listed in Section IV and who are experiencing benefit from therapy as evidenced by maintenance or normalization of calcium levels compared to baseline.

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.