PRIOR AUTHORIZATION POLICY

POLICY: Hypoparathyroidism – Yorvipath Prior Authorization Policy
- Yorvipath® (palopegteriparatide subcutaneous injection – Ascendis)

REVIEW DATE: 09/11/2024; selected revision 10/30/2024

OVERVIEW

Yorvipath, a parathyroid hormone (PTH) analog (PTH [1-34]), is indicated for the **treatment of hypoparathyroidism** in adults.[1]

Limitations of Use: Yorvipath has not been studied for acute post-surgical hypoparathyroidism.[1] Also, the titration scheme has only been evaluated in adults who first achieved an albumin-corrected serum calcium of at least 7.8 mg/dL utilizing calcium and active vitamin D treatment.

Within 2 weeks before the first Yorvipath dose, confirm serum 25(OH) vitamin D is within the normal range and albumin-corrected serum calcium is ≥ 7.8 mg/dL.[1]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Yorvipath. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Yorvipath as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Yorvipath to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Yorvipath is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Chronic Hypoparathyroidism.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient cannot be well-controlled on calcium supplements and active forms of vitamin D according to the prescriber; AND
     - **ii.** Patient has sufficient 25-hydroxyvitamin D stores (at baseline before initiating Yorvipath therapy) according to the prescriber; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has an albumin-corrected serum calcium concentration ≥ 7.8 mg/dL at baseline before initiating Yorvipath therapy; OR
       - **b)** Patient has an ionized serum calcium ≥ 4.4 mg/dL at baseline before initiating Yorvipath therapy; AND
     - **iv.** The medication is prescribed by or in consultation with an endocrinologist or a nephrologist.
   - **B)** Patient is Currently Receiving Yorvipath. Approve if the patient meets ALL of the following (i, ii, and iii):

i. Patient cannot be well-controlled on calcium supplements and active forms of vitamin D according to the prescriber; AND
ii. Patient has sufficient 25-hydroxyvitamin D stores (during Yorvipath therapy) according to the prescriber; AND
iii. Patient is responding to Yorvipath therapy, according to the prescriber.
Note: Response to Yorvipath therapy include reduction in the patient's oral calcium dose; reduction in the patient's active vitamin D dose; and maintenance of a stable albumin-corrected total serum calcium concentration.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Yorvipath is not recommended in the following situations:

1. **Acute Post-Surgical Hypoparathyroidism.** Yorvipath was not studied in patients with acute post-surgical hypoparathyroidism.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Yorvipath® subcutaneous injection [prescribing information]. Princeton, NJ: Ascendis; 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.