MEDICAL MUTUAL®

Drug Policy

Policy:	Yorvipath (palopegteriparatide subcutaneous injection - Ascendis)	Annual Review Date: 10/17/2024 Last Revised Date: 10/17/2024

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

This policy involves the use of Yorvipath. Prior authorization is recommended for pharmacy benefit coverage of Yorvipath. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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 be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Chronic Hypoparathyroidism.** Approve for 1 year if the patient meets ONE of the following conditions (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.

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.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Yorvipath has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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.