Pharmacy Policy Bulletin: J-1404 Yorvipath (palopegteriparatide) – Commercial and Healthcare Reform	
Number: J-1404	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1404-002	**Original Date:** 10/02/2024
Effective Date: 12/30/2024	**Review Date:** 10/02/2024

Drugs Product(s):	• Yorvipath (palopegteriparatide)
FDA-Approved Indication(s):	• Treatment of hypoparathyroidism in adults

Background:	• Yorvipath is a self-administered subcutaneous injection. • Hypoparathyroidism is a rare endocrine abnormality in which parathyroid gland dysfunction causes parathyroid hormone (PTH) deficiency. This can result in hypocalcemia, hyperphosphatemia, and increase neuromuscular irritability. Symptoms of hypoparathyroidism include myalgias, muscle spasms, twitching, new-onset seizures, and in extreme cases, tetany. • Yorvipath is a PTH analog and a prodrug of teriparatide (PTH(1-34)). PTH raises calcium by increasing calcium reabsorption in the kidneys, increasing absorption of calcium in the intestine and by increasing bone turnover which releases calcium into the circulation. PTH(1-34) released from Yorvipath maintains calcium and phosphate homeostasis by increasing serum calcium and decreasing serum phosphate, in turn increasing intestinal absorption of calcium and phosphate. • Prescribing Considerations: ○ Yorvipath has not been studied in acute-post surgical hypoparathyroidism. ○ Confirm an albumin-corrected serum calcium of at least 7.8 mg/dL using calcium and active vitamin D prior to treatment with Yorvipath. ○ Severe hypercalcemia has been reported with Yorvipath. The risk is highest when starting or increasing the dose of Yorvipath but can occur at any time. Monitor serum calcium and for signs and symptoms of hypercalcemia. ○ Severe hypocalcemia can occur with Yorvipath. The risk is highest when abruptly discontinued but may occur at any time. Hypocalcemia can

	result in seizures, refractory heart failure, and laryngospasm. Hypocalcemia in pregnancy may result in spontaneous abortion, premature or dysfunctional labor, and preeclampsia. Monitor patients for signs and symptoms of hypocalcemia. Treat hypocalcemia with an active form of vitamin D and calcium supplements. ○ Yorvipath is not recommended in patients at increased risk of osteosarcoma. ○ Orthostatic hypotension has been reported with Yorvipath. Monitor for signs and symptoms of orthostatic hypotension. ○ Concomitant use with digoxin may predispose to digitalis toxicity if hypercalcemia develops. With concomitant use, frequently measure serum calcium and digoxin levels, and monitor for signs and symptoms of digoxin toxicity. ○ The maximum recommended dosage is 30 mcg subcutaneously once daily. ○ Due to these risks, a 6 month initial authorization is recommended.

Approval Criteria

I. Initial Authorization
When a benefit, coverage of Yorvipath may be approved when all of the following criteria are met **(A. through D.)**:
- **A.** The member is 18 years of age or older.
- **B.** The member has a diagnosis of hypoparathyroidism. (ICD10: D82.1, E83.5, and E20, excluding E20.1)
- **C.** The prescriber attests that the member's albumin-corrected serum calcium level is ≥ 7.8 mg/dL.
- **D.** The member has established hypoparathyroidism despite treatment with calcium and active forms of vitamin D (e.g. calcitriol or alfacalcidol).

II. Reauthorization
When a benefit, reauthorization of Yorvipath may be approved when the following criterion is met **(A.)**:
- **A.** The prescriber attests improvement in total serum calcium from baseline.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Yorvipath has not been studied and should not be used in patients with acute post-surgical hypoparathyroidism.

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support their effectiveness and safety in other conditions.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Yorvipath [package insert]. Hellerup, Denmark: Ascendis Pharma Bone Diseases A/S.; August 2024.
2. Hans SK, Levine SN. Hypoparathyroidism. [Updated 2024 Feb 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available at: https://www.ncbi.nlm.nih.gov/books/NBK441899/. Accessed August 23, 2024
3. Aliya A. Khan, John P. Bilezikian, Maria Luisa Brandi, et, al.t, Evaluation and Management of Hypoparathyroidism Summary Statement and Guidelines from the Second International Workshop, *Journal of Bone and Mineral Research*, Volume 37, Issue 12, 1 December 2022, Pages 2568–2585.
4. Murray TM, Rao LG, Divieti P, Bringhurst FR. Parathyroid hormone secretion and action: evidence for discrete receptors for the carboxyl-terminal region and related biological actions of carboxyl- terminal ligands. *Endocr Rev*. 2005;26(1):78.