Optum Rx®

Yorvipath® (palopegteriparatide) – New orphan drug approval

- On August 12, 2024, Ascendis Pharma announced the FDA approval of Yorvipath (palopegteriparatide), for the treatment of hypoparathyroidism in adults.
    - 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.
- Hypoparathyroidism is a rare endocrine disease caused by insufficient levels of parathyroid hormone that impact multiple organs and affects an estimated 70,000 to 90,000 people in the U.S.
- Yorvipath is a parathyroid hormone analog and is the only drug currently available approved for hypoparathyroidism.
- The efficacy of Yorvipath was established in a randomized, double-blind, placebo-controlled study in 82 adults with hypoparathyroidism. During the double-blind period, patients were randomized to Yorvipath or placebo. The primary endpoint was overall response, based on: albumin-corrected serum calcium in the normal range; independence from conventional therapy; no increase in the study drug dose since week 22; no missing active vitamin D and calcium data since week 22; and study drug dose of 30 mcg or less once daily during the 26-week treatment period.
    - In the Yorvipath group, 68.9% of patients met the efficacy endpoint at week 26 compared with 4.8% of patients in the placebo group (treatment difference 64.2, 95% CI: 49.5, 78.8).
- Warnings and precautions for Yorvipath include risk of unintended changes in serum calcium levels related to number of daily injections and total delivered dose; serious hypercalcemia; serious hypocalcemia; potential risk of osteosarcoma; orthostatic hypotension; and risk of digoxin toxicity with concomitant use of digitalis compounds.
- The most common adverse reactions (≥ 5%) with Yorvipath use were injection site reactions, vasodilatory signs and symptoms, headache, diarrhea, back pain, hypercalcemia, and oropharyngeal pain.
- The recommended starting dosage of Yorvipath is 18 mcg once daily. Dosage adjustments should be made in 3 mcg increments or decrements. The Yorvipath dosage should not be increased more often than every 7 days. The Yorvipath dosage should not be decreased more often than every 3 days.
    - The recommended dosage range of Yorvipath is 6 to 30 mcg once daily.
    - Refer to the Yorvipath drug label for complete dosage and administration recommendations.
- Ascendis Pharma plans to launch Yorvipath by the first quarter 2025. Yorvipath will be available as single-patient-use prefilled pens:
    - 168 mcg/0.56 mL pen, labeled doses of 6, 9, or 12 mcg
    - 294 mcg/0.98 mL pen, labeled doses of 15, 18, or 21 mcg
    - 420 mcg/1.4 mL pen, labeled doses of 24, 27, or 30 mcg.

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