PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/11/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Yorvipath® (palopegteriparatide subcutaneous injection - Ascendis) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

FDA-Approved Indication

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.

CONDITIONS NOT COVERED

- **Yorvipath® (palopegteriparatide subcutaneous injection (Ascendis) is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

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

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/11/2024