CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Forteo (teriparatide)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include alendronate, risedronate, ibandronate tablet, and zoledronic acid QUANTITY LIMIT— 600 mcg/2.4 mL (1 pen) per month
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Forteo (teriparatide) injection is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

OSTEOPOROSIS

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Medication is being used for treatment of **one** the following:
   a) Osteoporosis in postmenopausal women;
   b) Primary or hypogonadal osteoporosis in men;
   c) Glucocorticoid-induced osteoporosis in men and women who have been taking ≥ 5 mg of prednisone (or equivalent) daily for ≥ 3 months; AND
3. Member is at high-risk for fracture as evidenced by **one** of the following:
   a) Bone mineral density (BMD) T-score –2.5 or below in the lumbar spine, femoral neck, proximal femur, 1/3 radius, or total hip;
   b) History of vertebral (spine) or hip fracture;
   c) T-score between –1 and –2.5 with a fragility fracture of proximal humerus, pelvis, or distal forearm;
   d) T-score between –1 and –2.5 with FRAX score of ≥ 20% for major osteoporotic fracture or ≥ 3% for hip fracture;
   e) Member is taking prednisone ≥ 30 mg/day and a cumulative dose of > 5 gm in the past year;
   f) Member is taking prednisone ≥ 7.5mg/day AND having greater than 10% BMD loss per year or a Z score < -3 at hip or spine; AND
4. Member meets **one** of the following drug trials:
   a) Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate);
   b) If oral bisphosphonate is not tolerated or contraindicated or if member has very high risk for fracture, must have a trial with IV bisphosphonate (e.g., zoledronic acid (Reclast), ibandronate) or Prolia (prior authorization required); AND
      **Note*: very high fracture risk is defined as having multiple fractures, T score of -3.5 or below, fracture while taking osteoporosis drug, FRAX > 30% for major osteoporosis fracture or 4.5% for hip fracture[2].
5. The total length of treatment for parathyroid hormone analogs (abaloparatide, teriparatide) has not exceeded 24 months in the member's lifetime.

6. **Dosage allowed:** 20 mcg subcutaneously once daily.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Treatment length has not exceeded 24 months in lifetime; AND
2. Chart notes have been provided showing stable or increase in bone mineral density, with no evidence of new fractures or vertebral fracture progression.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Forteo (teriparatide injection) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Bone metastases from solid tumors
- Giant Cell Tumor of Bone
- Hypercalcemic disorder
- Multiple Myeloma
- Paget's disease
- Pediatric and young adult members with open epiphyses
- Prior external beam or implant radiation involving the skeleton
- Skeletal malignancies

DATE	ACTION/DESCRIPTION
08/02/2019	New policy for Forteo created.
07/31/2020	Removed uncorrected hypocalcemia and dental disease. Removed list of reasons oral bisphosphonates cannot be used. Removed risk factor appendix. Removed calcium and vitamin D requirements. Modified osteoporosis definitions to include GC-induced high-risk groups. Specified length of oral bisphosphonate trial for 12 months. Added age requirement. Specified 2nd line trials to be any IV bisphosphonate or Prolia. Added no more than 2 years of treatment to initial and reauth. Changed length of initial approval to 12 months. Changed reauth language to say stable or increase BMD with no evidence of new fractures.

References:

1. Forteo [prescribing information]. Indianapolis, IN: Lilly USA, LLC; April, 2020.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2020. *Endocr Pract*. 2020 May;26(5):564-570.
3. Cosman, F., de Beur, S.J., LeBoff, M.S. et al. Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporos Int 25, 2359–2381 (2014).
4. Compston J, Cooper A, Cooper C, et al. UK clinical guideline for the prevention and treatment of osteoporosis. *Arch Osteoporos*. 2017;12(1):43. doi:10.1007/s11657-017-0324-5.
5. Leder BZ. Optimizing Sequential and Combined Anabolic and Antiresorptive Osteoporosis Therapy. *JBMR Plus*. 2018;2(2):62-68. Published 2018 Feb 27.
6. Buckley L, Guyatt G, Fink HA, et al. 2017 American college of rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. *Arthritis Rheumatol*. 2017 Aug;69(8):1521-1537.
7. Rao SS, Budhwar N, Ashfaque A. Osteoporosis in men. *Am Fam Physician*. 2010 Sep 1;82(5):503-8.

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