CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Forteo (teriparatide)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Forteo (teriparatide) was initially approved by the FDA in 2002 and is a parathyroid hormone analog. It is indicated for the treatment of postemenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with primary or hypogonadal osteoporosis at high risk of fracture, and for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

Forteo (teriparatide) will be considered for coverage when the following criteria are met:

Osteoporosis in Postmenopausal Women

For **initial** authorization:

1. Member is a postmenopausal woman; AND
2. Member has a diagnosis of osteoporosis, as evidenced by one of the following:
   a) Bone mineral density (BMD) T-score –2.5 or below in the lumbar spine, femoral neck, total proximal femur, or 1/3 radius;
   b) Low-trauma spine or hip fracture (regardless of BMD);
   c) Osteopenia (T-score between –1 and –2.5) with a fragility fracture of proximal humerus, pelvis, or distal forearm;
   d) Osteopenia (T-score between –1 and –2.5) with FRAX fracture probability of ≥ 20% for major osteoporotic fracture or ≥ 3% for hip fracture; AND
3. Member meets one of the following:
   a) Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast), ibandronate) OR
   b) Member has very high risk for fracture (e.g., having multiple fractures, very low T score (-3.0 or below), T-score -2.5 or below plus fractures, fractures while taking osteoporosis drug, FRAX > 30% for major osteoporosis fracture or 4.5% for hip fracture); AND
4. The total length of treatment for parathyroid hormone analogs (abaloparatide, teriparatide) has not exceeded 24 months in the member's lifetime; AND
5. For Forteo requests, trial and failure of teriparatide.
6. **Dosage allowed/Quantity limit:** 20 mcg subcutaneously once daily (1 pen per 28 days)

If all the above requirements are met, the medication will be approved for up to 24 months.

For **reauthorization**:

1. Treatment beyond 24 months will not be authorized.

Osteoporosis in Men

For **initial** authorization:
1. Member is a male 18 years of age or older; AND
2. Medication is being used to treat osteoporosis; AND
3. Member is at high-risk for fracture as evidenced by one of the following:
   a) Hip or vertebral fracture without major trauma
   b) BMD of the spine, femoral neck, and/or total hip is 2.5 SD or more below the mean of normal young white males (T-score -2.5 or less)
   c) T-score between −1.0 and −2.5 in the spine, femoral neck, or total hip plus a 10-yr risk of experiencing any fracture ≥ 20% or 10-yr risk of hip fracture ≥ 3% using FRAX; AND
4. Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast)), unless not tolerated or contraindicated; AND
5. The total length of treatment for parathyroid hormone analogs (abaloparatide, teriparatide) has not exceeded 24 months in the member's lifetime; AND
6. For Forteo requests, trial and failure of teriparatide.
7. **Dosage allowed/Quantity limit:** 20 mcg subcutaneously once daily (1 pen per 28 days)

If all the above requirements are met, the medication will be approved for up to 24 months.

For **reauthorization**:
1. Treatment beyond 24 months will not be authorized.

Glucocorticoid-Induced Osteoporosis

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Medication is being used to treat Glucocorticoid-induced osteoporosis in a member who is initiating or continuing systemic glucocorticoids equivalent to daily 7.5 mg or greater of prednisone and will remain on therapy for at least 6 months; AND
3. Member is at high-risk for fracture as evidenced by at least one of the following:
   a) Prior osteoporotic fragility fracture(s)
   b) Postmenopausal female or male age 50 and older with hip or spine bone mineral density (BMD) T-score -2.5 or below
   c) Age 40 or older with FRAX 10-year risk of:
      i) Major osteoporotic fracture of 20% or above; OR
      ii) Hip fracture of 3% or above; AND
4. Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast)), unless not tolerated or contraindicated; AND
5. The total length of treatment for parathyroid hormone analogs (abaloparatide, teriparatide) has not exceeded 24 months in the member's lifetime; AND
6. For Forteo requests, trial and failure of teriparatide.
7. **Dosage allowed/Quantity limit:** 20 mcg subcutaneously once daily (1 pen per 28 days)

If all the above requirements are met, the medication will be approved for up to 24 months.

For **reauthorization**:
1. Treatment beyond 24 months will not be authorized.

CareSource considers Forteo (teriparatide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/01/2019	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.
04/26/2022	Transferred to new template. Added references. Split each indication into separate sections. Removed "stable" from renewal; BMD should increase. Postmenopausal women: Added criterion for those at very high risk of fracture. Men: Clarified definition of high risk. GIO: Revised who is eligible for treatment to match guidelines.
02/01/2023	Adding trial and failure of teriparatide.
02/17/2023	All indications: Removed renewal criteria and changed initial authorization period to total of 24 months. Removed zoledronic acid trial for very high risk postmenopausal women.

References:

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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.
8. Gregson CL, Armstrong DJ, Bowden J, et al. UK clinical guideline for the prevention and treatment of osteoporosis. *Arch Osteoporos*. 2022;17(1):58. Published 2022 Apr 5. doi:10.1007/s11657-022-01061-5
9. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2012;97(6):1802-1822. doi:10.1210/jc.2011-3045
10. Compston J. Glucocorticoid-induced osteoporosis: an update. *Endocrine*. 2018;61(1):7-16. doi:10.1007/s12020-018-1588-2

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