Forteo (teriparatide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Forteo (teriparatide) Injection pen	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Forteo (teriparatide) may be approved for the following:

I. Individual has one of the following:
   A. Individual is a postmenopausal female with a diagnosis of osteoporosis [defined as bone mineral density (BMD) T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture)]at high risk for fracture[1]; **OR**

   B. Individual is a male diagnosed with primary or hypogonadal osteoporosis [defined as BMD T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on a history of a low trauma fracture (fragility fracture)] at high risk for fracture[1] using to increase bone mass; **OR**

   C. Individual has a diagnosis of osteoporosis [defined as BMD T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on history of low trauma fracture (fragility fracture)] associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone for at least 3 months) at high risk for fracture[1].

AND

II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred oral bisphosphonate;

   Preferred agents: Alendronate tablet (generic Fosamax), alendronate oral solution (generic Fosamax oral solution), risedronate (generic Actonel)

OR

III. The preferred agents is not FDA-approved and does not have an accepted off-label use per the off-label policy for the prescribed indication and the requested non-preferred agent does;

OR

IV. Individual meets one of the following:
    A. Individual is a postmenopausal female at very high risk for fracture as defined by one or more of the following (AACE/ACE 2020):
        1. Recent fracture (within the past 12 months)
        2. Fractures while on approved osteoporosis therapy
        3. Multiple fractures
        4. Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids)
        5. Very low T-score (less than -3.0)
        6. High risk for falls or history of injurious falls
        7. Very high fracture probability by FRAX (fracture risk assessment tool) (e.g. major osteoporosis fracture >30%, hip fracture >4.5%) or other validated fracture risk algorithm;

        OR
    B. The individual has been refractory to a prior trial of a bisphosphonate; **OR**
    C. The individual is intolerant to or has a contraindication to a bisphosphonate as defined by:
        1. Hypersensitivity to TWO bisphosphonates (one of which must be alendronate); **OR**
        2. Inability to stand or sit upright for at least 30 minutes; **OR**
        3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, atrophic gastritis, etc.); **OR**
        4. Uncorrected hypocalcemia; **OR**
        5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents and zoledronic acid or creatinine clearance less than 30 mL/min for risedronate and ibandronate;

AND

V. Individual is not using Forteo (teriparatide) in combination with any of the following:
    A. Prolia (denosumab); **OR**
    B. Bisphosphonates: **OR**
    C. Evista (raloxifene); **OR**
    D. Miacalcin/Fortical (calcitonin nasal spray); **OR**
    E. Reclast (zoledronic acid); **OR**
    F. Tymlos (abaloparatide); **OR**
    G. Evenity (romosozumab-aqqg); **OR**
    H. Another teriparatide agent.

AND

Continuation of therapy with Forteo (teriparatide) may be approved if the following criteria are met:

I. There is confirmation of clinically significant response to therapy (including but not limited to confirmation of no new fractures reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction); **AND**
II. If individual has been on therapy ≥ 24 months of treatment, a repeat BMD demonstrates a stable or increase in BMD; **AND**
III. Individual is not using Forteo (teriparatide) in combination with any of the following:
    A. Prolia (denosumab)
    B. Bisphosphonates
    C. Evista (raloxifene)
    D. Miacalcin/Fortical (calcitonin nasal spray)
    E. Reclast (zoledronic acid)
    F. Tymlos (abaloparatide);
    G. Evenity (romosozumab-aqqg);
    H. Another teriparatide agent.

Requests for Forteo (teriparatide) may not be approved when the above criteria are not met and for all other indications.

Notes:

1. High risk for fracture is defined as the following:
    A. History of osteoporotic fracture; or
    B. Multiple risk factors for fractures including but not limited to: Prior low-trauma fracture as an adult, advanced age, gender, ethnicity , low bone mineral density, low body weight, family history of osteoporosis, use of glucocorticoids (daily dosage equivalent to 5mg per day or greater prednisone for at least 3 months), cigarette smoking, excessive alcohol consumption (3 or more drinks/day), secondary osteoporosis (such as, rheumatoid arthritis), early menopause, height loss or kyphosis, fall risk and low calcium intake; ; or
    C. Failure or intolerance to other osteoporosis therapies.
2. A failure of other osteoporosis therapies, otherwise known as refractory disease, may be defined as a decline in BMD while on therapy (≥5%) or a fragility fracture while on therapy.

Key References:

1. 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 Update. *Endocrine Practice*. 2020;26(1):1-46.

2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 18, 2021.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2020. Updated periodically.
6. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 5, May 2019, Pages 1595–1622, https://doi.org/10.1210/jc.2019-00221.
7. Gilsenan A, Midkiff K, Harris D, et al. Assessing the incidence of osteosarcoma among teriparatide users based on Medicare Part D and US State Cancer Registry Data. Pharmacoepidemiol Drug Saf. 2020 Dec;29(12):1616-1626. Available at: https://onlinelibrary.wiley.com/doi/10.1002/pds.5103 Accessed July 8, 2021.
8. Gilsenan A, Midkiff K, Harris D, et al. Teriparatide Did Not Increase Adult Osteosarcoma Incidence in a 15-Year US Postmarketing Surveillance Study. J Bone Miner Res. 2021 Feb;36(2):244-251. Available at: https://asbmr.onlinelibrary.wiley.com/doi/10.1002/jbmr.4188 Accessed July 8, 2021.
9. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update, The Journal of Clinical Endocrinology & Metabolism, Volume 105, Issue 3, March 2020, Pages 587-594.
10. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.