

**Pharmacy Prior Authorization  
Clinical Guidelines - Injectable Osteoporosis Medications**

Forteo<sup>®</sup> (teriparatide)    Prolia<sup>®</sup> (denosumab)    Tymlos<sup>®</sup> (abaloparatide)    zoledronic acid

**Authorization Guidelines:**

**Treatment of Osteoporosis in Postmenopausal Women and Men (Zoledronic acid, Prolia, Forteo, and Tymlos (for women only)):**

**Note: Tymlos (where indicated) is the preferred agent. Requests for Forteo require trial and failure of Tymlos in addition to clinical criteria.**

- Diagnosis of osteoporosis (T-score less than -2.5 **OR** fragility fracture at the hip, spine, wrist, arm, rib, or pelvis)
- Member has ONE of the following:
  - Therapeutic failure of an oral or intravenous (IV) bisphosphonate despite compliance (including new fracture or reduction in bone mineral density (BMD) per recent dual energy X-ray absorptiometry (DEXA) scan after 2 years of oral bisphosphonate)
  - Contraindication or severe intolerance to oral bisphosphonate (for example, current upper gastrointestinal (GI) symptoms, inability to swallow, or inability to remain in an upright position after oral bisphosphonate administration for the required length of time)
- **In addition for men:** Testosterone level is normal for the lab reference range. If member is hypogonadal, testosterone replacement therapy should be prescribed before starting treatment with an injectable osteoporosis agent unless the member has a history of prostate cancer.

**Prevention of Osteoporosis in Postmenopausal Women (Zoledronic acid):**

- Diagnosis of osteopenia (T-score between -1.0 and -2.5) and at high risk for osteoporosis (OP) fracture (Fracture Risk Assessment Tool (FRAX) risk greater than or equal to 3.0% for hip fracture or greater than or equal to 20% for any major osteoporosis (OP)-related fracture **OR** multiple risk factors for fracture) \*See Additional information for details
- Member has ONE of the following:
  - Therapeutic failure of an oral or intravenous (IV) bisphosphonate despite compliance (including new fracture or reduction in bone mineral density (BMD) per recent dual energy X-ray absorptiometry (DEXA) scan after 2 years of oral bisphosphonate)
  - Contraindication or severe intolerance to oral bisphosphonate (for example, current upper gastrointestinal (GI) symptoms, inability to swallow, or inability to remain in an upright position after oral bisphosphonate administration for the required length of time)

**Glucocorticoid-Induced Osteoporosis (Zoledronic acid, Forteo):**

- Member meets ONE of the following:
  - Postmenopausal woman or a man over 50 years old and has received, or is expected to receive, prednisone over 7.5mg/day (or equivalent) for longer than 3 months
  - Premenopausal woman or a man less than 50 years old with a history of fragility fracture and has received, or is expected to receive, prednisone over 7.5mg/day (or equivalent) for greater than 3 months

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- Therapeutic failure of an oral or intravenous (IV) bisphosphonate despite compliance (including new fracture or reduction in bone mineral density (BMD) per recent dual energy X-ray absorptiometry (DEXA) scan after two years of oral bisphosphonate)
- Contraindication or severe intolerance to oral bisphosphonate (e.g., current upper gastrointestinal (GI) symptoms, inability to swallow, or inability to remain in an upright position after oral bisphosphonate administration for the required length of time)

**Bone Metastases of Cancer and Multiple Myeloma: (zoledronic acid):**

- Member has one of the following diagnoses:
  - Solid tumor with bone metastases
  - Castration-resistant prostate cancer with bone metastases
  - Multiple myeloma

**Increase of Bone Mass in Men on Androgen Deprivation Therapy for Prostate Cancer Without Bone Metastases: (Prolia, zoledronic acid):**

- Member is at high risk for osteoporosis (OP) fracture (Fracture Risk Assessment Tool (FRAX) risk of greater than or equal to 3.0% for hip fracture or greater than or equal to 20% for any major osteoporosis (OP)-related fracture, or multiple risk factors for fracture) \*See Additional information for details
- Member has ONE of the following:
  - Therapeutic failure of an oral or intravenous (IV) bisphosphonate despite compliance (including new fracture or reduction in bone mineral density (BMD) per recent dual energy X-ray absorptiometry (DEXA) scan after 2 years of oral bisphosphonate)
  - Contraindication or severe intolerance to oral bisphosphonate (e.g., current upper gastrointestinal (GI) symptoms, inability to swallow, or inability to remain in an upright position after oral bisphosphonate administration for the required length of time)

**Increase of Bone Mass in Women on Aromatase Inhibitory therapy for Breast Cancer WITHOUT Bone Metastases: (Prolia, zoledronic acid):**

- Member is postmenopausal or premenopausal with a diagnosis of osteoporosis (T-score less than -2.5 OR fragility fracture at the hip, spine, wrist, arm, rib, or pelvis)
- Member has ONE of the following:
  - Therapeutic failure of an oral or intravenous (IV) bisphosphonate despite compliance (including new fracture or reduction in bone mineral density (BMD) per recent dual energy X-ray absorptiometry (DEXA) scan after 2 years of oral bisphosphonate)
  - Contraindication or severe intolerance to oral bisphosphonate (e.g., current upper gastrointestinal (GI) symptoms, inability to swallow, or inability to remain in an upright position after oral bisphosphonate administration for the required length of time)

**Hypercalcemia of Malignancy: (zoledronic acid):**

- Member has moderate or severe hypercalcemia (refer to additional information for details) associated with malignancy
- Member is receiving vigorous saline hydration with a goal of increasing urine output to about 2 L/day

**Paget's Disease of Bone: (zoledronic acid):**

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- Member has bone specific alkaline phosphatase greater than 2 times the upper limit of normal (ULN) **or** has symptoms related to active Paget's (i.e., pain at the site of the pagetic lesion)
- Member has normal serum calcium, phosphorus, and 25-hydroxyvitamin D (based on the reference range for the lab). Abnormalities should be treated before starting intravenous (IV) bisphosphonates
- Member has one of the following:
  - Therapeutic failure of an oral or intravenous (IV) bisphosphonate despite compliance (including new fracture or reduction in bone mineral density (BMD) per recent dual energy X-ray absorptiometry (DEXA) scan after two years of oral bisphosphonate)
  - Contraindication or severe intolerance to oral bisphosphonate (e.g., current upper gastrointestinal (GI) symptoms, inability to swallow, or inability to remain in an upright position after oral bisphosphonate administration for the required length of time)

**Initial Approval:**

- Paget's Disease: one treatment
- Hypercalcemia from Malignancy: one treatment
- Osteoporosis: two years
- All other indications: two years

**Note:** Cumulative use of abaloparatide (Tymlos) and teriparatide (Forteo) for more than two years during a member's lifetime is not recommended

**Renewal:**

Documentation to support member is benefiting from therapy (e.g. improved or stabilized bone mineral density (BMD), no new fractures etc.)

- Paget's Disease: one treatment
  - If bone specific alkaline phosphatase rises after initial treatment **OR** if member has symptoms
  - Bisphosphonates usually induce remission, therefore long-term approval is usually **NOT** appropriate
- Hypercalcemia from Malignancy: Retreatment not recommended unless new occurrence
- Osteoporosis: Members with stable bone mineral density (BMD) without fractures on treatment may be appropriate for a drug holiday after 4-5 years of treatment. Continue treatment if bone mineral density (BMD) has worsened or if member had fractures on treatment
- All other indications: two years if member meets criteria for initial approval

**Quantity Limits:**

- Forteo: one pen per 28 days
- Prolia: one vial/syringe per 168 days (six months)
- Tymlos: one pen per 30 days
- Zoledronic Acid:
  - For Treatment of Osteoporosis and Glucocorticoid-Induced Osteoporosis (GIOP): one, 5mg vial per year

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- For Prevention of Osteoporosis: one, 5mg vial every 2 years
- For Multiple Myeloma (MM) or Bone Metastases: one, 4mg vial per 21 days

### **Additional Information:**

It is recommended by American Association of Clinical Endocrinologists (AACE) and the Endocrine Society that the patient's serum 25-hydroxyvitamin D level be  $\geq 30$  ng/mL and patients should receive calcium and vitamin D from diet and/or supplements to improve effectiveness of the medications and to prevent hypocalcemia.

Fracture Risk Assessment Tool (FRAX) Calculator: <http://www.shef.ac.uk/FRAX/tool.jsp?locationValue=9>

Severe Hypercalcemia = albumin-corrected calcium (cCa) greater than 12 mg/dL [3.0 mmol/L]

Formula: albumin-corrected calcium (cCa) in mg/dL = Ca in mg/dL + 0.8 (4.0 g/dL - member albumin [g/dL]).

Major Risk factors for Osteoporotic Fractures:

- a. low body mass index
- b. previous fragility fracture
- c. parental history of hip fracture
- d. glucocorticoid treatment (refer to specific criteria above for this indication)
- e. current smoking
- f. alcohol intake of 3 or more units per day
- g. rheumatoid arthritis
- h. secondary causes of osteoporosis

### **References:**

1. Forteo<sup>®</sup> (teriparatide). Prescribing information. Eli Lilly and Company, Indianapolis, IN; Revised Oct 2016.
2. Boniva Injection<sup>®</sup> (ibandronate). Prescribing information. Roche Laboratories, Inc., Nutley, NJ; Revised December 2016.
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4. Prolia<sup>®</sup> (denosumab). Prescribing information. Amgen Manufacturing Limited, Thousand Oaks, CA; Revised May 2017.
5. Tymlos<sup>®</sup> (abaloparatide). Prescribing information. Radius Health, Inc, Waltham, MA; Revised April 2017.
6. Qaseem A, Forciea M, McLean Robert et al. Treatment of low bone density or osteoporosis to prevent fractures in men and women: A clinical practice guideline update from the American College of Physicians. [https://www.acponline.org/acp\\_policy/guidelines/treatment\\_of\\_low\\_bone\\_density\\_or\\_osteoporosis\\_to\\_prevent\\_fractures\\_2017.pdf](https://www.acponline.org/acp_policy/guidelines/treatment_of_low_bone_density_or_osteoporosis_to_prevent_fractures_2017.pdf). Published May 9, 2017. Accessed August 15, 2017.
7. NCCN: National Comprehensive Cancer Network. NCCN Clinical Practice Guideline in Oncology: Prostate Cancer. [http://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf). Version 1.2015. Accessed August 15, 2017.
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9. Use of adjuvant bisphosphonates and other bone-modifying agents in breast cancer: a Cancer Care Ontario and American Society of Clinical Oncology clinical practice guideline. <https://guidelines.gov/summaries/summary/51038/use-of-adjuvant-bisphosphonates-and-other-bonemodifying-agents-in-breast-cancer-a-cancer-care-ontario-and-american-society-of-clinical-oncology-clinical-practice-guideline?q=Osteoporosis+>. Accessed March 22, 2018