AETNA BETTER HEALTH®
Prior Authorization guideline for Injectable Osteoporosis Agents

Applicable Injectable Osteoporosis Agents

- Forteo (teriparatide)
- Prolia (denosumab)
- Tymlos (abaloparatide) - preferred
- zoledronic acid

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

Authorization guidelines

For the treatment of osteoporosis in members who meet the following criteria (zoledronic acid, Prolia, Forteo, and Tymlos (women only)):

1. Diagnosis of osteoporosis:
   a. T-score less than -2.5
   or
   b. Fragility fracture at the hip, spine, wrist, arm, rib, or pelvis
2. Documentation of ONE of the following:
   a. Therapeutic failure of an oral or intravenous (IV) bisphosphonate despite compliance (including new fracture or reduction in BMD per recent DEXA scan after 2 years of oral bisphosphonate)
   b. Contraindication or severe intolerance to oral bisphosphonate (e.g., current upper GI symptoms, inability to swallow, or inability to remain in an upright position after oral bisphosphonate administration for the required length of time)
3. 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 patient has a history of prostate cancer.

For the prevention of osteoporosis in postmenopausal women: (Zoledronic acid)

1. Diagnosis of osteopenia (T-score between -1.0 and -2.5) and at high risk for osteoporosis (OP) fracture (FRAX risk greater than or equal to 3% for hip fracture or greater than or
equal to 20% for any major OP-related fracture OR multiple risk factors for fracture
*See Additional information for details

2. Documentation of ONE of the following:
   a. Therapeutic failure of an oral or intravenous (IV) bisphosphonate despite compliance (including new fracture or reduction in BMD per recent DEXA scan after 2 years of oral bisphosphonate)
   b. Contraindication or severe intolerance to oral bisphosphonate (e.g., current upper GI symptoms, inability to swallow, or inability to remain in an upright position after oral bisphosphonate administration for the required length of time)

For the treatment of corticosteroid-induced osteoporosis (zoledronic acid, Forteo):
   1. Member meets ONE of the following:
      a. 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
   b. 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
   AND
   2. Documentation of ONE of the following:
      a. Therapeutic failure of an oral or intravenous (IV) bisphosphonate despite compliance (including new fracture or reduction in BMD per recent DEXA scan after 2 years of oral bisphosphonate)
      b. Contraindication or severe intolerance to oral bisphosphonate (e.g., current upper GI symptoms, inability to swallow, or inability to remain in an upright position after oral bisphosphonate administration for the required length of time)

For the treatment of Paget’s disease of bone in men and women (zoledronic acid)
   1. 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)
   2. Member has normal serum calcium, phosphorus, and 25-hydroxyvitamin D. Abnormalities should be treated before starting IV bisphosphonates
   3. Documentation of ONE of the following:
      a. 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)
b. Contraindication or severe intolerance to oral bisphosphonate (e.g., current upper 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 of Multiple Myeloma:** (zoledronic acid)

Member has ONE of the following diagnoses:

1. Solid tumor with bone metastases
2. Castration-resistant prostate cancer with bone metastases
3. Multiple myeloma

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

1. Member is at high risk for osteoporosis (OP) fracture (Fracture Risk Assessment Tool (FRAX) risk of greater than or equal to 3% for hip fracture or greater than or equal to 20% for any major OP-related fracture, or multiple risk factors for fracture) *See Additional information for details
2. Documentation of ONE of the following:
   a. Therapeutic failure of an oral or intravenous (IV) bisphosphonate despite compliance (including new fracture or reduction in BMD per recent DEXA scan after 2 years of oral bisphosphonate)
   b. Contraindication or severe intolerance to oral bisphosphonate (e.g., current upper 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:**

**Bone Metastases:** (Prolia, zoledronic acid)

1. 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)
2. Documentation of ONE of the following:
   a. Therapeutic failure of an oral or intravenous (IV) bisphosphonate despite compliance (including new fracture or reduction in BMD per recent DEXA scan after 2 years of oral bisphosphonate)
   b. Contraindication or severe intolerance to oral bisphosphonate (e.g., current upper 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)

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

Authorization and Limitations

Note: Cumulative use of abaloparatide (Tymlos) and teriparatide (Forteo) for more than two (2) years during a member’s lifetime is not recommended

Initial Approval:
- Paget’s Disease: 1 treatment
- Hypercalcemia from Malignancy: 1 treatment
- Osteoporosis: 2 years
- All other indications: 2 years

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: 1 treatment
  - If bone specific alkaline phosphatase rises after initial treatment OR if patient has symptoms
  - Bisphosphonates usually induce remission, therefore long-term approval is usually NOT appropriate
- Hypercalcemia from Malignancy: Retreatment not recommended unless new occurrence
- Osteoporosis: Patients with stable BMD without fractures on treatment may be appropriate for a drug holiday after 4-5 years of treatment. Continue treatment if BMD has worsened or if patient had fractures on treatment
- All other indications: 2 years if patient 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
  - For Prevention of Osteoporosis: one, 5mg vial every 2 years
  - For Multiple Myeloma (MM) or Bone Metastases: one, 4mg vial per 21 days

Last Review: 8/2018
Previous PARP Approval: 11/2017
Current PARP Approval: 9/2018
**Additional Information**

Injectable Osteoporosis Agents are **NOT** covered for members with the following criteria:  
- Use not approved by the FDA; **AND**  
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

It is recommended by the American Association of Clinical Endocrinologists (AACE) and the Endocrine Society that the patient’s serum 25-hydroxyvitamin D level be ≥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 than12 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:  
1. low body mass index  
2. previous fragility fracture  
3. parental history of hip fracture  
4. glucocorticoid treatment (refer to specific criteria above for this indication)  
5. current smoking  
6. alcohol intake of 3 or more units per day  
7. rheumatoid arthritis  
8. secondary causes of osteoporosis

**Medically Necessary** — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.
The determination is based on medical information provided by the Member, the Member’s family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References: