Authorization Guidelines:

Treatment of Osteoporosis in Postmenopausal Women and Men (Zoledronic acid, Prolia, Forteo, and Tymlos (for women only)):
- Diagnosis of osteoporosis (T-score <-2.5 OR fragility fracture at the hip, spine, wrist, arm, rib, or pelvis)
- Member has ONE of the following:
  - Therapeutic failure on oral 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)
- In addition for men: Testosterone level is normal. 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 ≥3.0% for hip fracture or ≥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 on oral 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)

Glucocorticoid-Induced Osteoporosis (Zoledronic acid, Forteo):

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

- Therapeutic failure on oral 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:
  o Solid tumor with bone metastases
  o Castration-resistant prostate cancer with bone metastases
  o 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 ≥3.0% for hip fracture or ≥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:
    o Therapeutic failure on oral 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)
    o 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 <-2.5 OR fragility fracture at the hip, spine, wrist, arm, rib, or pelvis)
  • Member has ONE of the following:
    o Therapeutic failure on oral 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)
    o 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):
• Member has bone specific alkaline phosphatase >2x 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. Abnormalities should be treated before starting intravenous (IV) bisphosphonates
• Member has one of the following:
  o Therapeutic failure on oral 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 GIOP: one, 5mg vial per year
  - For Prevention of Osteoporosis: one, 5mg vial every 2 years
  - For 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 ≥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.

Severe Hypercalcemia = albumin-corrected calcium (cCa) >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:
- low body mass index
- previous fragility fracture
- parental history of hip fracture
- glucocorticoid treatment (refer to specific criteria above for this indication)
- current smoking
- alcohol intake of 3 or more units per day
- rheumatoid arthritis
- secondary causes of osteoporosis

References: