maryland physicians care
Medicaid with a Heart

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PHARMACY PRIOR AUTHORIZATION
Clinical Guideline – INJECTABLE OSTEOPOROSIS MEDICATIONS
Forteo® (teriparatide) Prolia® (denosumab) Zoledronic acid

FDA Approved Indications:

Treatment of Osteoporosis in Postmenopausal Women:

- **Zoledronic acid** is indicated for treating osteoporosis in postmenopausal women including those at high risk for fracture. In postmenopausal women with osteoporosis, diagnosed by bone mineral density (BMD) or prevalent vertebral fracture, Zoledronic acid reduces the incidence of fractures (hip, vertebral and non-vertebral osteoporosis-related fractures). In patients at high risk of fracture, defined as a recent low trauma hip fracture, Zoledronic acid reduces the incidence of new clinical fractures.
- **Prolia** and **Forteo** are indicated for the treatment of postmenopausal women with osteoporosis *at high risk for fracture*, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures and Forteo reduces the risk of vertebral and nonvertebral fractures.

Prevention of Osteoporosis in Postmenopausal Women:

- **Zoledronic acid** is indicated for prevention of osteoporosis in postmenopausal women with osteopenia.

Osteoporosis in Men:

- **Zoledronic acid** is indicated to increase bone mass in men with osteoporosis.
- **Prolia** and **Forteo** are indicated to increase bone mass in men with osteoporosis *at high risk for fracture*, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Glucocorticoid-Induced Osteoporosis:

- **Zoledronic acid** is indicated for the treatment and prevention of glucocorticoid-induced osteoporosis in men and women who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and who are expected to remain on glucocorticoids for at least 12 months.
- **Forteo** is indicated for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Paget's Disease of Bone:

- **Zoledronic acid** is indicated for treatment of Paget's disease of bone in men and women. Treatment is indicated in patients with Paget's disease of bone with elevations in serum alkaline phosphatase of two times or higher than the upper limit of the age-specific normal reference range, or those who are symptomatic, or those at risk for complications from their disease.

Authorization Guidelines:

Treatment of Osteoporosis in Postmenopausal Women and Men: (Zoledronic acid, Prolia, and Forteo)

- Diagnosis of osteoporosis (T-score <-2.5 **OR** previous hip or vertebral fracture)
- Patient's 25-hydroxyvitamin D level is >20 ng/mL. Patients who are vitamin D deficient should have vitamin D replaced (i.e., 50,000 IU weekly) before starting treatment with an injectable osteoporosis agent.
- Patient has ONE of the following:
  - Therapeutic failure on oral bisphosphonate despite compliance (including new fracture or reduction in BMD per recent DEXA scan after 2 years of oral bisphosphonate)
  - 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)
- **In addition for men**: Testosterone level is normal. If patient 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.

Prevention of Osteoporosis in Postmenopausal Women: (Zoledronic acid)

- Diagnosis of osteopenia (T-score between -1.0 and -2.5) and at high risk for OP fracture (FRAX risk ≥3.0% for hip fracture or ≥20% for any major OP-related fracture **OR** multiple risk factors for fracture) *See Additional information for details
- Patient's 25-hydroxyvitamin D level is >20 ng/mL. Patients who are vitamin D deficient should have vitamin D replaced (i.e., 50,000 IU weekly) before starting treatment with an injectable osteoporosis agent.
- Patient has ONE of the following:
  - Therapeutic failure on oral bisphosphonate despite compliance (including new fracture or reduction in BMD per recent DEXA scan after 2 years of oral bisphosphonate)
  - 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)

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
- Patient's 25-hydroxyvitamin D level is >20 ng/mL. Patients who are vitamin D deficient should have vitamin D replaced (i.e., 50,000 IU weekly) before starting treatment with an injectable osteoporosis agent.
- Patient has ONE of the following:
  - Therapeutic failure on oral bisphosphonate despite compliance (including new fracture or reduction in BMD per recent DEXA scan after 2 years of oral bisphosphonate)
  - 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)

Paget's Disease of Bone: (zoledronic acid)

- Patient has bone specific alkaline phosphatase ≥2x ULN **OR** has symptoms related to active Paget's (i.e., pain at the site of the pagetic lesion)
- Patient has normal serum calcium, phosphorus, and 25-hydroxyvitamin D. Abnormalities should be treated before starting IV bisphosphonates
- Patient meets ONE of the following:
  - Therapeutic failure on a compliant, 2-month trial of oral bisphosphonate
  - 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)

Initial Approval:

- Paget's Disease: 1 treatment
- Osteoporosis: 5 years
- All other indications: 2 years

Renewal:

- 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
- 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
- Note: Forteo is NOT recommended for longer than 2 years due to the risk of osteosarcoma

Additional Information:

1. It is recommended that all patients should receive ≥1200 mg of elemental calcium and ≥1000 mg of vitamin D from diet and/or supplements to improve effectiveness of the medications and to prevent hypocalcemia.
2. FRAX Calculator: http://www.shef.ac.uk/FRAX/tool.jsp?locationValue=9
3. Severe Hypercalcemia = albumin-corrected calcium (cCa) ≥12 mg/dL [3.0 mmol/L]
   Formula: cCa in mg/dL=Ca in mg/dL + 0.8 (4.0 g/dL - patient albumin [g/dL]).
4. 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:

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