Therapeutic Class or Brand Name: Osteoporosis Agents

Applicable Drugs: Evenity (romosozumab), Forteo® (teriparatide), Prolia® (denosumab), Tymlos (abaloparatide), Xgeva® (denosumab)

Preferred: teriparatide (generic)

Non-preferred: Evenity (romosozumab), Forteo® (teriparatide), Prolia® (denosumab), Tymlos (abaloparatide), Xgeva® (denosumab)

Date of Origin: 11/6/2024

Date Last Reviewed / Revised: 11/6/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of one of the following A through G and must meet the criteria under applicable diagnosis:

A. Osteoporosis

i. Documentation of one of the following:

1. Postmenopausal osteoporosis
2. Male with primary osteoporosis or hypogonadal osteoporosis

ii. Patient has osteoporosis and/or is at high risk for fracture and meets one of the following 1 or 2:

1. Documented baseline bone mineral density (BMD) T-score of -2.5 or less.
2. Have osteopenia (T-score between -1 and -2.5) and a history of previous fractures or glucocorticoid use for at least 3 months at a dose of 5 mg per day of prednisone (or equivalent).

iii. Documented treatment failure on an oral or IV bisphosphonate or contraindication to all bisphosphonate therapy (i.e., alendronate, ibandronate, risedronate, zoledronic acid, etc.)

iv. Documentation that the patient will also take calcium 1000 mg daily (excluding Forteo® [teriparatide]) and at least 400 IU vitamin D daily.

v. Minimum age requirement: 18 years old.

B. Glucocorticoid-induced osteoporosis

i. Patient has osteoporosis and/or is at high risk for fracture defined by meeting either criterion 1 or 2:

1. Documented baseline bone mineral density (BMD) T-score of -2.5 or less.
2. Have osteopenia (T-score between -1 and -2.5) and a history of previous fractures or glucocorticoid use for at least 3 months at a dose of 5 mg per day of prednisone (or equivalent).

ii. Documentation that treatment duration with glucocorticoids will be 6 months or longer.

iii. Documented treatment failure on an oral or IV bisphosphonate or contraindication to all bisphosphonate therapy (i.e., alendronate, ibandronate, risedronate, zoledronic acid, etc.).

iv. Documentation that the patient will also take calcium 1000 mg daily (excluding Forteo® [teriparatide]) and at least 400 IU vitamin D daily.

v. Minimum age requirement: 18 years old.

C. Bone metastases from solid tumors and multiple myeloma

i. Documented treatment failure on IV bisphosphonate therapy (i.e., pamidronate, zoledronic acid, etc.) or contraindication to all IV bisphosphonates.

ii. Minimum age requirement: 18 years old.

D. Giant cell tumor of bone

i. Tumor is unresectable, or surgical resection is contraindicated.

ii. Patient is an adult or skeletally mature adolescent (defined by at least 1 mature long bone (i.e. closed epiphyseal growth plate of the humerus).

iii. Minimum age requirement: 13 years old and weighing greater than 45 kg

E. Hypercalcemia of malignancy

i. Patient has a documented albumin-corrected calcium greater than 12.5 mg/dL (3.1 mmol/L).

ii. Documented treatment failure on IV bisphosphonate therapy (i.e., pamidronate, zoledronic acid, etc.) or contraindication to all IV bisphosphonates.

iii. Minimum age requirement: 18 years old.

F. Nonmetastatic prostate cancer treatment-induced bone loss

i. Documentation of androgen deprivation therapy

ii. Minimum age requirement: 18 years old.

G. Breast cancer treatment-induced bone loss

i. Documentation of adjuvant aromatase inhibitor therapy

ii. Minimum age requirement: 18 years old.

II. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines. See Appendix Table 1.

III. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- Evenity should not be initiated in patients who have had an MI or stroke within the preceding year.
- Xgeva: Skeletal-related events in patients with multiple myeloma. Hypocalcemia.
- Prolia: Hypocalcemia, Pregnancy
- Coadministration of Xgeva with Prolia
- Forteo: Patients with Paget's disease of bone. Pediatric or young adult patients with open epiphyses. Patients with prior external beam or implant radiation therapy involving the skeleton. Patients with bone metastases, history of skeletal malignancies, metabolic bone diseases other than osteoporosis, or hypercalcemic disorders. Use of Forteo for more than 2 years during a patients' lifetime.

Other Criteria

- Treatment failure is defined as the progression of bone loss as recorded by bone mineral density measurements or occurrence of an osteoporotic fracture after a minimum of a 12-month trial of oral bisphosphonate therapy or IV bisphosphonate therapy (i.e., alendronate, ibandronate, risedronate, zoledronic acid, etc.)

Quantity / Days Supply Restrictions

- Requested quantities not exceeding limits listed in Appendix Table 1.

Approval Length

- **Authorization:**
  - Forteo: 24 months with no option for re-authorization.
  - All other agents: 1 year
- **Re-Authorization:**
  - Evenity, Forteo: N/A
  - An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

- Table 1. Select FDA Indications and Quantity Limits For Osteoporosis Agents

Osteoporosis Agents
Postmenopausal women with osteoporosis
• Forteo: One 2.4mL prefilled injectable pen per 28 days • Evenity: Two 1.17ml prefilled syringes per 28 days • Prolia: One 1ml prefilled syringe every 6 months • Tymlos: One 1.56ml pen per 28 days
Primary/hypogonadal osteoporosis in men
• Forteo: One 2.4mL prefilled injectable pen per 28 days • Prolia: One 1ml prefilled syringe every 6 months • Tymlos: One 1.56ml pen per 28 days
Glucocorticoid-induced osteoporosis
• Forteo: One 2.4mL prefilled injectable pen per 28 days • Prolia: One 1ml prefilled syringe every 6 months
Bone metastases from solid tumors and multiple myeloma
• Xgeva: One 1.7ml vial per 28 days
Giant cell tumor of bone and hypercalcemia of malignancy
• Xgeva: Three 1.7ml vial for 28 days, then one vial every 28 days
Prostate or Breast Cancer Treatment – Induced Bone Loss
• Prolia: One 1ml prefilled syringe every 6 months

REFERENCES

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3. Prolia. Prescribing information. Amgen Inc; 2023. Accessed November 7, 2024. http://pi.amgen.com/united_states/prolia/prolia_pi.pdf.
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