Therapeutic Class or Brand Name: Osteoporosis Agents

Applicable Drugs: Bomyntra (denosumab-bnht), Bonsity (teriparatide), Conexxence (denosumab-bnht), Evenity (romosozumab), Forteo® (teriparatide), Jubbonti (denosumab-bbdc), Osenvelt (denosumab-bmwo), Prolia® (denosumab), Stoboclo (denosumab-bmwo), Tymlos (abaloparatide), Xgeva® (denosumab)

Preferred: teriparatide (generic), Osenvelt (denosumab-bmwo), Stoboclo (denosumab-bmwo)

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

Formulary Shield: Bomyntra (denosumab-bnht), Conexxence (denosumab-bnht)

Date of Origin: 11/6/2024

Date Last Reviewed / Revised: 7/8/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV 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 (e.g., alendronate, ibandronate, risedronate, zoledronic acid, etc.)

iv. Documentation that the patient will also take calcium 1000 mg daily (except for requests for teriparatide) and at least 400 IU vitamin D daily.

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 (e.g., alendronate, ibandronate, risedronate, zoledronic acid, etc.).

iv. Documentation that the patient will also take calcium 1000 mg daily (except for requests for teriparatide) and at least 400 IU vitamin D daily.

C. Bone metastases from solid tumors and multiple myeloma

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

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 (e.g., pamidronate, zoledronic acid, etc.) or contraindication to all IV bisphosphonates.

F. Nonmetastatic prostate cancer treatment-induced bone loss

i. Documentation of androgen deprivation therapy

G. Breast cancer treatment-induced bone loss

i. Documentation of adjuvant aromatase inhibitor therapy

II. Minimum age requirement: 18 years old, except for the treatment of Giant Cell Tumor of Bone, for which the age requirement is 13 years old, as noted in section I.E.iii.

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

IV. 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 (romosozumab) should not be initiated in patients who have had an MI or stroke within the preceding year.
- Coadministration of more than one denosumab-containing product.
- Denosumab products: hypocalcemia, pregnancy.
- Teriparatide products:
    - Use of teriparatide for more than 2 years during a patient's lifetime.
    - 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

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 or IV bisphosphonate therapy (e.g., alendronate, ibandronate, risedronate, zoledronic acid, etc.)

Quantity / Days Supply Restrictions

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

Approval Length

- **Authorization:**
    - Teriparatide: 24 months, with no option for re-authorization.
    - All other agents: 1 year.
- **Re-Authorization:**
    - Evenity, teriparatide: reauthorization not available.
    - All other agents: 1 year, with an updated letter of medical necessity or progress notes showing that 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
• Teriparatide: One 2.24mL prefilled injectable pen per 28 days • Evenity: Two 1.17ml prefilled syringes per 28 days • Prolia and biosimilars: One 1ml prefilled syringe every 6 months • Tymlos: One 1.56ml pen per 28 days
Primary/hypogonadal osteoporosis in men
• Teriparatide: One 2.24mL prefilled injectable pen per 28 days • Prolia and biosimilars: One 1ml prefilled syringe every 6 months • Tymlos: One 1.56ml pen per 28 days
Glucocorticoid-induced osteoporosis
• Teriparatide: One 2.24mL prefilled injectable pen per 28 days • Prolia and biosimilars: One 1ml prefilled syringe every 6 months
Bone metastases from solid tumors and multiple myeloma
• Xgeva and biosimilars: One 1.7ml vial per 28 days
Giant cell tumor of bone and hypercalcemia of malignancy
• Xgeva and biosimilars: Three 1.7ml vials for 28 days, then one vial every 28 days
Prostate or Breast Cancer Treatment – Induced Bone Loss
• Prolia and biosimilars: One 1ml prefilled syringe every 6 months

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