CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Prolia (denosumab) and biosimilars (Jubbonti, Stoboclo)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Prolia, approved by the FDA in 2010, is a monoclonal antibody that inhibits the RANK ligand (RANKL) and is approved for the treatment of postmenopausal women with osteoporosis at high risk for fracture, treatment to increase bone mass in men with osteoporosis at high risk for fracture, and treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture. It is also approved to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and for treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Prolia (denosumab) and biosimilars (Jubbonti, Stoboclo) will be considered for coverage when the following criteria are met:

Osteoporosis in Postmenopausal Women

For **initial** authorization:

1. Member is a postmenopausal woman; AND
2. Member has a diagnosis of osteoporosis, as evidenced by one of the following:
   a) Bone mineral density (BMD) T-score –2.5 or below in the lumbar spine, femoral neck, total proximal femur, or 1/3 radius;
   b) Low-trauma spine or hip fracture (regardless of BMD);
   c) Osteopenia (T-score between –1 and –2.5) with a fragility fracture of proximal humerus, pelvis, or distal forearm;
   d) Osteopenia (T-score between –1 and –2.5) with FRAX fracture probability of ≥ 20% for major osteoporotic fracture or ≥ 3% for hip fracture; AND
3. Member meets one of the following:
   a) Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast), ibandronate) OR
   b) Member has very high risk for fracture (e.g., having multiple fractures, very low T score (-3.0 or below), T-score -2.5 or below plus fractures, fractures while taking osteoporosis drug, FRAX > 30% for major osteoporosis fracture or 4.5% for hip fracture) AND has had a trial of zoledronic acid; AND
4. If the request is for Prolia, the member has tried and failed Jubbonti or Stoboclo.
5. **Dosage allowed/Quantity limit:** 60 mg subQ every 6 months. (1 syringe (1 mL) per 6 months)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing positive clinical response such as stable or increased BMD or no evidence of new fractures or vertebral fracture progression.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

Osteoporosis in Men

For **initial** authorization:
1. Member is a male 18 years of age or older; AND
2. Medication is being used to treat osteoporosis; AND
3. Member is at high-risk for fracture as evidenced by one of the following:
   a) Hip or vertebral fracture without major trauma
   b) BMD of the spine, femoral neck, and/or total hip is 2.5 SD or more below the mean of normal young white males (T-score -2.5 or less)
   c) T-score between −1.0 and −2.5 in the spine, femoral neck, or total hip plus a 10-yr risk of experiencing any fracture ≥ 20% or 10-yr risk of hip fracture ≥ 3% using FRAX; AND
4. Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast)), unless not tolerated or contraindicated; AND
5. If the request is for Prolia, the member has tried and failed Jubbonti or Stoboclo.
6. **Dosage allowed/Quantity limit:** 60 mg subQ every 6 months. (1 syringe (1 mL) per 6 months)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing positive clinical response such as stable or increased BMD or no evidence of new fractures or vertebral fracture progression.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

Glucocorticoid-Induced Osteoporosis

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication is being used for glucocorticoid-induced osteoporosis; AND
3. Member is initiating or continuing systemic glucocorticoids (GC) equivalent to 2.5 mg/day or greater of prednisone and will remain on therapy for more than 3 months; AND
4. Member meets one of the following (a, b, or c):
   a) Moderate fracture risk:
      i) Age 40 years or greater and both of the following:
         (1) FRAX 10-year risk of major osteoporotic fracture of 10 to 19%, hip >1 to <3%, or BMD t-score between -1 and -2.4; AND
         (2) Inadequate response to at least 12 months of a bisphosphonate; OR
      ii) Age <40 years and both of the following:
         (1) GC 7.5 mg/day or greater for 6 months or longer AND BMD z-score less than -3 OR significant BMD loss (more than the least significant change of DXA); AND
         (2) Inadequate response to at least 12 months of a bisphosphonate.
   b) High fracture risk: Age 40 years or greater and BMD t-score ≤−2.5 but >−3.5 or FRAX 10-year risk of major osteoporotic fracture of 20 to 29% or hip 3 to 4.4%.

c) Very high fracture risk: Prior osteoporotic fracture, BMD t-score -3.5 or less, FRAX 10-year risk of major osteoporotic fracture of 30% or greater or hip 4.5% or greater, or GC 30 mg/day or greater for more than 30 days or cumulative 5 g/year or more; AND
5. If the request is for Prolia, the member has tried and failed Jubbonti or Stoboclo.
6. **Dosage allowed/Quantity limit:** 60 mg subQ every 6 months. (1 syringe (1 mL) per 6 months)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing positive clinical response such as stable or increased BMD or no evidence of new fractures or vertebral fracture progression; AND
2. One of the following:
   a) Continuing GC, or
   b) Remains at very high or high risk of fracture with BMD t-score ≤−2.5, or fragility fracture occurring after ≥12 months of therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

Bone Loss (prostate cancer)

For **initial** authorization:
1. Member is a male 18 years of age or older; AND
2. Member has a diagnosis of non-metastatic prostate cancer; AND
3. Member is receiving androgen deprivation therapy (e.g., goserelin, leuprolide, degarelix); AND
4. Member is at high risk for fracture, as defined by one of the following:
   a) T-score less than -2.5 (osteoporosis) in the femoral neck, total hip, or lumbar spine
   b) Prior fragility fracture(s)
   c) FRAX score of ≥ 20% for major osteoporotic fracture or ≥ 3% for hip fracture; AND
5. Member has had an inadequate response to 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast)), unless not tolerated or contraindicated; AND
6. If the request is for Prolia, the member has tried and failed Jubbonti or Stoboclo.
7. **Dosage allowed/Quantity limit:** 60 mg subQ every 6 months. (1 syringe (1 mL) per 6 months)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Member continues to be at high risk for fracture due to taking androgen deprivation therapy; AND
2. Chart notes have been provided showing positive clinical response such as stable or increased BMD or no evidence of new fractures or vertebral fracture progression.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

Bone Loss (breast cancer)

For **initial** authorization:
1. Member is a postmenopausal female; AND
2. Member has a diagnosis of breast cancer; AND
3. Member is currently receiving an adjuvant aromatase inhibitor (e.g., anastrozole, letrozole); AND
4. Member is at high risk for fracture, as defined by one of the following:

a) T-score < -2.0 in the femoral neck, total hip, or lumbar spine
b) Has two or more of the following risk factors: prior fragility fracture(s), parental hip fracture, diabetes, 2 or more falls in the past year, rheumatoid arthritis, BMI < 20, current smoking, more than 2 alcoholic drinks per day, greater than 7.5 mg/day glucocorticoid use > 3 months
c) Has T-score <1.0 plus one of the above risk factors; AND

5. Member has had an inadequate response to 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast)), unless not tolerated or contraindicated; AND
6. If the request is for Prolia, the member has tried and failed Jubbonti or Stoboclo.
7. **Dosage allowed/Quantity limit:** 60 mg subQ every 6 months. (1 syringe (1 mL) per 6 months)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Member continues to be at high risk for fracture due to receiving aromatase inhibitor therapy; AND
2. Chart notes have been provided showing positive clinical response such as stable or increased BMD or no evidence of new fractures or vertebral fracture progression.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Prolia (denosumab) and biosimilars (Jubbonti, Stoboclo) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/19/2019	New policy for Prolia created
08/13/2020	For osteoporosis: added age requirement; removed Appendix of risk factors for fracture; added diagnostic criteria for GC-induced; removed exclusions (uncorrected hypocalcemia, dental disease, Xgeva within past 6 months); removed vitamin D & calcium requirement; removed reasons oral bisphosphonate cannot be used; changed trial to 12 months of oral or IV bisphosphonate; changed approval length to 12 months. For bone loss due to cancer drugs: added age requirement; redefined diagnostic requirements according to latest guidelines; removed exclusions (uncorrected hypocalcemia, dental disease, Xgeva within past 6 months); removed vitamin D & calcium requirement; trial specified to be 12 months or oral or IV bisphosphonate; changed approval length to 12 months.
04/26/2022	Transferred to new template. Added and updated references. Split each indication into separate sections. Postmenopausal women: Added criterion for those at very high risk of fracture. Men: Clarified definition of high risk. GIO: Revised who is eligible for treatment to match guidelines. Breast cancer: Specified postmenopausal. Updated high risk definition (Waqas, et al). Prostate cancer: Corrected high risk definition.
05/16/2024	Edited renewal criteria to positive clinical response with examples. Updated reference (clinician's guide). GIO: Updated references. Changed prednisone 7.5 mg and 6 months to 2.5 mg and 3 months, added moderate and very high risk criteria instead of just high risk, updated criteria for high risk, added continuation of GC or remain at high to very high risk for renewal (Humphrey et al.; ACR). Postmenopausal women: Added reference (Shoback et al).

09/19/2025	Changed policy title to include biosimilars. Added trial of a biosimilar.

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