Osteoporosis Medications Prior Authorization Criteria

Risedronate (Actonel)- NON- FORMULARY

1. Does member have a funded condition with indication for treatment with Risedronate?
   - Prevention or treatment of post-menopausal osteoporosis
   - Prevention or treatment of glucocorticoid induced osteoporosis
   - Osteoporosis in men
   - Paget's disease

   a. Yes- Continue to question 2
   b. No- Deny Cat 1 *if non funded condition*
   Deny Cat 3 *if for non – FDA approved use*

2. Has member has an inadequate response (See definition below-must use for 6 months or more) to or is unable to tolerate therapy with formulary bisphosphonates Alendronate and Ibandronate while also using Vitamin D and calcium supplements?

   a. Yes- Continue to question 3
   b. No- Deny Cat 15- *Member has not tried and failed preferred formulary alternatives.*

3. Is the dosing and administration correct
   - 5 mg once daily
   - 35 mg weekly
   - 150 mg monthly
   - 30 mg once daily for 2 months (Paget's disease only)

   a. Yes- Approve
   b. No- Deny Cat 3- *Dosing is outside FDA approved guidelines*

- Inadequate response is defined as decline in BMD over 5% where the patient is taking the medication correctly OR Fracture occurs while on bisphosphonate therapy
- Contraindications / intolerance to oral bisphosphonates include:
  - Patients with esophageal disorders
  - Unable to follow dosing requirement of remaining upright for 30 to 60 minutes
- Contraindications / intolerance to oral and IV bisphosphonates include:
  - Severe bone pain with bisphosphonate therapy
  - Chronic kidney disease (eGFR< 30 ml/min)

Osteoporosis Medications Prior Authorization Criteria

Evista (raloxifene) – Formulary- PA required

1. Does the member have a funded condition or relevant co morbid condition on the OHP prioritized list?
   a. Yes- Continue to question 2
   b. No- Deny Cat 1- for non-funded condition

2. Does member have any of the following conditions with indication for treatment with Evista?
   - Prevention and treatment of osteoporosis in postmenopausal women
   - Risk reduction of breast cancer in postmenopausal women with osteoporosis or at high risk of invasive breast cancer.
   a. Yes- Continue to question 3
   b. No- Deny Cat 3- *Medication is being prescribed outside of FDA approved use*

3. Has the member has inadequate response (after 6 months or more) or intolerance to preferred treatment alternatives of alendronate *and* ibandronate *and* calcitonin *(if appropriate) while also on Vitamin D and calcium supplements?

   a. Yes- Continue to question 5
   b. No- Continue to question 4

4. Is the member at high risk of invasive breast cancer?
   High risk for invasive breast cancer is defined as 1 or more of the following:
   - Five year predicted risk for breast cancer is 3% or more
   - History of breast biopsy with atypical hyperplasia or lobular carcinoma in situ
   - One or more first degree relatives with breast cancer

   a. Yes- Continue to question 5
   b. No- Deny Cat 5- *Member has not tried and failed preferred treatment alternatives for osteoporosis and/or have high risk of invasive breast cancer as defined above*.

5. Does the member have a history of or present as high risk for VTE or non-vertebral (hip) fracture?
   a. Yes- Forward to medical director for medical appropriateness evaluation- Raloxifene has a black box warning for increased risk of VTE and stroke and reduction of risk of non-vertebral fractures has not been substantiated with its use.
   b. No- Continue to question 6
6. Is the dosing correct – 60 mg once daily
   a. Yes- approve for 1 year
   b. No- Deny Cat 3 – *Dosing falls outside FDA approved guidelines*

*Calcitonin nasal spray appropriate for use in women more than 5 years postmenopausal where hip fracture is not primary concern or member has bone pain from previous fracture.

Osteoporosis Medications Prior Authorization Criteria

Forteo (teriparatide)- NON- FORMULARY

1. Does the member have a funded condition or relevant co morbid condition on the OHP prioritized list?
   a. Yes- Continue to question 2
   b. No- Deny Cat 1- *Member condition is not a funded condition on the OHP prioritized list*

2. Does the member have a diagnosis of osteoporosis with one of the following?
   -a very low BMD (T-score of – 3.5 or lower)
   - History of prevalent vertebral fracture
   - Low trauma or fragility fracture (fracture from minor trauma such as falling from a standing height or less)
      a. Yes- Continue to question 3
      b. No- Forward to medical director- Medication is indicated only in cases of osteoporosis with high risk of fracture as defined above.

3. Has member has an inadequate response to or contraindication to bisphosphonate therapy (at least two oral agents and one IV agent) AND Evista (women only) while also on Vitamin D and calcium supplements?

   a. Yes- Continue to question 4
   b. No- Deny Cat 15- *Member has not tried and failed formulary alternatives*

4. Is the member receiving concomitant bisphosphonate, SERM or Prolia?
   a. Yes- Deny Cat 3- *Medication is not indicated for use with these medications*
   b. No- Continue to question 5

5. Is the dosing correct (20 mcg SQ once daily) and has the member used medication for less than 2 years?

   a. Yes- May approve up to 2 years total treatment
   b. No- Deny Cat 3- *Dosing is outside of FDA approved guidelines and safety and efficacy of medication beyond 2 years of treatment has not been studied.*

Osteoporosis Medications Prior Authorization Criteria

Prolia (Denosumab)

1. Does the member have a funded condition or relevant co morbid condition on the OHP prioritized list?
   a. Yes- continue to question 2
   b. No- Deny Cat 1 – *Member does not have a funded condition on the OHP prioritized list*

2. Does the member have one of the following conditions with indication for treatment with Prolia?
   - Androgen induced bone loss in men with prostate cancer
   - Aromatase inhibitor induced bone loss in women with breast cancer
   - Treatment of osteoporosis in post-menopausal women
   - Treatment of osteoporosis in men

   a. Yes- Continue to question 3
   b. No- Deny Cat 3- *Medication being used outside of FDA approved indications*

3. Has member had inadequate response or intolerance to therapy with ALL of the following while also using Vitamin D and calcium supplements?
   - At least 2 oral bisphosphonates
   - IV bisphosphonates
   - Raloxifene (Evista- Women only)
   - Calcitonin (if appropriate for patient to use)

   a. Yes- Continue to question 5
   b. No- Continue to question 4

4. Does member have one of the following:
   - Androgen induced bone loss in men with prostate cancer
   - Aromatase inhibitor induced bone loss in women with breast cancer
   - Severe renal impairment (CrCl < 35 ml/minute)

   a. Yes- Continue to question 5
   b. No- Forward to Medical Director – Member has not had inadequate response to or intolerance of preferred treatment alternatives or condition requiring treatment with denosumab

5. Is dosing appropriate – all above indications are 60 mg SQ once every 6 months
   a. Yes- Approve
   b. No- Deny Cat 3- Dosing is not within FDA guidelines