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Gateway Health
Prior Authorization Criteria
Xgeva (denosumab) and Prolia (denosumab)

All requests for Xgeva (denosumab) and/or Prolia (denosumab) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Xgeva (denosumab), Prolia (denosumab) Prior Authorization Criteria:

For all requests for Xgeva® (denosumab), Prolia® (denosumab) all of the following criteria must be met:

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be prescribed by on in consultation with an oncologist or hematologist (Xgeva only)
- An attestation of the following:
    - The member is receiving routine dental exams due to the risk of osteonecrosis of the jaw (ONJ).
    - The member does not have hypocalcemia
    - Ongoing monitoring of calcium levels during therapy and adequate supplementation with calcium and vitamin D

Requests for Xgeva® (denosumab):

Coverage may be provided with a diagnosis for prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors

Coverage may be provided with a diagnosis of giant cell tumor of bone and the following criteria is met:

- Members must be 12 years of age or older
- Members must be skeletally mature
- The tumor must be unresectable or surgical resection is likely to result in severe morbidity

Coverage may be provided with a diagnosis of hypercalcemia of malignancy and the following criteria is met:

- Documentation of an albumin-corrected calcium of > 12.5mg/dl (3.1 mmol/L) despite treatment with IV bisphosphonate therapy within the previous 30 days

Requests for Prolia® (denosumab)

For all requests for Prolia® (denosumab) all of the following criteria must be met:

- The member must be at moderate or high risk for fracture defined by one of the following:
    - A documented T-score between -1.0 and -2.5 at the lumbar spine, total hip, femoral neck, or 33% radius and one of the following:
        - Is on an aromatase inhibitor
        - Is on androgen deprivation therapy
        - History of osteoporotic fracture
        - The 10-year probability for major osteoporotic fracture is ≥20% or the 10-year probability of hip fracture is ≥3% based on the U.S. adapted World Health Organization (WHO) algorithm (also known as FRAX)
    - History of a fragility fracture as an adult
    - The member is on prednisone ≥7.5mg/day (or equivalent for at least 3 months and planning to continue therapy for at least 6 months and has one of the following:
        - A z score <-3 at hip or spine
        - A >10% per year bone loss of BMD at hip or spine
    - The member must currently be on or recently (with in the last year) taken a glucocorticoid steroid and have one of the following:
        - FRAX (glucocorticoid-adjusted) 10 year risk for major osteoporotic fracture ≥ 10%
        - FRAX (glucocorticoid-adjusted) 10 year risk for hip fracture > 1%
    - The member was recently on (within the past year) prednisone ≥30 mg/day and a cumulative dose of > 5 gm
    - A documented T-score of less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or 33% radius
- Must have tried (for at least 1 year each) and failed one oral bisphosphonate therapy and intravenous zoledronic acid unless contraindicated, intolerant, or member is experiencing an increased amount of fractures while on therapy

Coverage may be provided with a diagnosis of decreasing bone mass in women with breast cancer

Coverage may be provided with a diagnosis of glucocorticoid-induced osteoporosis and the following criteria is met:

- The member must currently be on or recently (with in the last year) taken a glucocorticoid steroid

Coverage may be provided with a diagnosis of decreasing bone mass in men with non-metastatic prostate cancer

Coverage may be provided with a diagnosis of decreasing bone mass in men with osteoporosis

Coverage may be provided with a diagnosis of postmenopausal osteoporosis in women

- **Initial Duration of Approval:** 12 months
- **Reauthorization Criteria:**
  - For Xgeva
    - For hypercalcemia of malignancy:
      - Documentation the member has corrected serum calcium ≤ 11.5 mg/dL (2.9 mmol/L)
      - For all other diagnoses for there is chart documentation of clinical improvement or stabilization of disease
  - For Prolia:
      - Documentation of clinical improvement or stabilization of disease
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.