ZOLEDRONIC ACID (ZOMETA®), (RECLAST®)	
Length of Authorization	
Zometa	Initial Approval: 12 months and may be renewed
Reclast	• Prevention of osteoporosis in post-menopausal women: Coverage is provided for 24 months and may be renewed. • All other indications: Coverage is provided for 12 months and may be renewed (unless otherwise specified)
FDA Indications	
Zometa • Treatment of Hypercalcemia of malignancy • Patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy Reclast • Treatment and prevention of postmenopausal osteoporosis • Treatment to increase bone mass in men with osteoporosis • Treatment and prevention of glucocorticoid-induced osteoporosis	
Clinical Criteria for Approval	
This medication will be covered with prior authorization when the following criteria are met: 1. Zometa A. Coverage is provided in the following conditions: i. Hypercalcemia of malignancy ii. Multiple myeloma iii. Bone metastases from solid tumors iv. Prevention of skeletal related events in men with castration-recurrent prostate cancer v. Prevention of bone loss associated with aromatase inhibitor therapy for breast cancer in post-menopausal women or premenopausal women on adjuvant ovarian suppression vi. Prevention of bone loss associated with androgen deprivation therapy in men with prostate cancer 2. Reclast A. Coverage is provided in the following conditions: i. Treatment and prevention of postmenopausal osteoporosis a. Patient experienced severe intolerance, ineffective response **±**, or has contraindications***** to oral bisphosphonate therapy; **OR** b. Patient had a prior fragility fracture or is at especially high fracture risk	

Note: patients discontinuing treatment with denosumab due to a reduction in fracture risk (i.e., no longer high or very high risk) require subsequent antiresorptive therapy in order to prevent accelerated bone mineral density loss and increase in fracture risk. Coverage is provided for **one** administration for this use prior to temporary discontinuation of intravenous antiresorptive therapy

ii. Treatment to increase bone mass in men with osteoporosis
    a. Patient experienced severe intolerance, ineffective response **±**, or has contraindications***** to oral bisphosphonate therapy; **OR**
    b. Patient had a prior fragility fracture or is at especially high fracture risk
iii. Treatment and prevention of glucocorticoid-induced osteoporosis
    a. Patient experienced severe intolerance, ineffective response **±**, or has contraindications***** to oral bisphosphonate therapy; **OR**
    b. Patient had a prior fragility fracture or is at especially high fracture risk
iv. Treatment of Paget's disease of bone in men and women
    a. Serum alkaline phosphatase is two times or higher than the upper limit of the age-specific reference range; **OR**
    b. Patient is symptomatic; **OR**
    c. Patient is at risk for complications from their disease
v. Prevention or treatment of osteoporosis in men with prostate cancer during androgen deprivation therapy
vi. Treatment of osteopenia/osteoporosis in patients with systemic mastocytosis

Clinical Criteria for Continued Approval

This medication will have continued coverage with prior authorization when the following criteria are met:

- Absence of unacceptable toxicity from the drug (e.g., renal toxicity, osteonecrosis of the jaw, atypical femoral fractures, hypocalcemia, incapacitating pain in the bone/joint/muscle, etc.); **AND**

1. Reclast
    A. Disease response as indicated by the following:
        I. Osteoporosis indications:
            i. Absence of fractures; **OR**
            ii. Increase in bone mineral density compared to pretreatment baseline; **AND**
                a. Patients who have received 3 years of bisphosphonate therapy should be re-evaluated with a DXA or serum marker for bone turnover [i.e., serum C-terminal crosslinking telopeptide (CTX)]; **AND**

b. Those patients at low-to-moderate risk of fractures should be considered for a temporary discontinuation of bisphosphonate for up to 5 years (re-assess risk at 2 to 4 year intervals to determine if earlier re-initiation is necessary)

iii. Paget's Disease: normalization of serum alkaline phosphatase (SAP) or a reduction of 75% from baseline in total SAP excess (defined as the difference between the measured level and midpoint of normal range)

2. Zometa
   A. Disease response as indicated by the following:
      I. Bone metastases/MM: absence/delay in skeletal-related events (e.g., pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression)
      II. Hypercalcemia of Malignancy: corrected serum calcium 5 11.5 mg/Dl
      III. Prevention of bone loss/SRE in cancer patients:
         i. Absence of fractures; **OR**
         ii. Increase in bone mineral density compared to pretreatment baseline

KEY

± Ineffective response is defined as one or more of the following:

- Decrease in T-score in comparison with baseline T-score from DXA scan
- Patient has a new fracture while on bisphosphonate therapy

*** Examples of contraindications to oral bisphosphonate therapy include the following:**

- Documented inability to sit or stand upright for at least 30 minutes
- Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia