



## Prior Authorization Approval Criteria

### *Reclast (zoledronic acid)*

**Generic name:** Zoledronic acid

**Brand name:** Reclast

**Medication class:** Bisphosphonate

**FDA-approved uses:**

- Treatment of Paget's disease of the bone in men and women
- Treatment of postmenopausal osteoporosis
- Treatment of osteoporosis in men
- Treatment and prevention of glucocorticoid-induced osteoporosis.

**Available dosage forms:** 5 mg/100 mL bottle (ready to use)

**Usual dose:**

*Paget's disease:* 5 mg infused over not less than 15 minutes

*Postmenopausal osteoporosis:* 5 mg infused over not less than 15 minutes; adjust dose based on serum creatinine measured prior to dose based on package insert

*Osteoporosis in men:* 5 mg infused over not less than 15 minutes

*Treatment and prevention of glucocorticoid-induced osteoporosis:* 5 mg infused over not less than 15 minutes

**Duration of therapy:** to be determined by physician.

*Paget's disease:*

- Single 5 mg dose
- Retreatment can be considered in patients who have relapsed.

*Postmenopausal osteoporosis:*

- Single dose up to 5 mg once yearly
- May be re-dosed on a once-yearly basis (studies only dosed up to 3 years)

*Treatment of osteoporosis in men*

- Single dose of 5 mg once yearly

*Treatment and prevention of glucocorticoid-induced osteoporosis*

- Single dose of 5 mg once yearly

**Approximate cost per dose:** \$1,200 per dose (based on AWP 2010)

**Criteria for use:** (bullet points below are all inclusive unless otherwise noted)

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Patient's creatinine clearance must be greater than or equal to 35 mL/min

**Reclast for Paget's disease:**

- Serum Alk Phos levels  $\geq 2 \times$  ULN for age-specific reference range
- Symptomatic disease (bone pain, hearing loss, bone deformities, fractures, arthritis)
- At risk of complications from Paget's disease (ex. osteoarthritis, heart failure, kidney stones, broken bones)
- Patient also receiving calcium and vitamin D

**Reclast for postmenopausal osteoporosis:**

- Tried and failed or intolerant of at least two oral bisphosphonates.

**Reclast for osteoporosis in men:**

- Tried and failed or intolerant of at least two oral bisphosphonates.

**Reclast for treatment and prevention of glucocorticoid-induced osteoporosis:**

- Tried and failed or intolerant of at least two oral bisphosphonates.

**Criteria for continuation of therapy:**

- Initial therapy was tolerated
- *For Paget's disease:* retreatment can be considered in patients who have relapsed, based on increases in serum alkaline phosphatase, or in those who failed to achieve normalization of their serum alkaline phosphatase, or in those patients with symptoms.
- *For postmenopausal osteoporosis:* demonstrated increase in BMD

**Cautions:**

- Osteonecrosis of the jaw has been reported with bisphosphonates, including zoledronic acid
- Increased incidence of atrial fibrillation in studies of Reclast vs. placebo in postmenopausal osteoporosis; however, causal relationship not clearly established

**Monitoring:**

- Fluid status
- Calcium, magnesium, phosphate, serum creatinine levels
- Duration of infusion cannot be  $< 15$  minutes

**Contraindications:**

- Hypocalcemia
- Pregnancy and lactation
- Hypersensitivity to the active ingredient or any of the excipients

- Concurrent use of aminoglycosides or loop diuretics due to increased risk of hypocalcemia
- Use with potentially nephrotoxic drugs such as NSAIDs
- Use of Reclast in patients currently using Zometa because the active ingredient in both is zoledronic acid, resulting in significantly increased risk of renal failure

**Not approved if:**

- Above criteria are not met
- Patient has any contraindications to the use of zoledronic acid.

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_