

**Regence BlueCross BlueShield of Oregon • Regence BlueShield
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Medication Policy Manual

Policy No: dru158

Topic: Reclast[®], zoledronic acid

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Revised Date: July 17, 2009

Next Review Date: July 2010

Effective Date: December 1, 2008

IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Zoledronic acid (Reclast[®]) is a bisphosphonate, a medication used to treat or prevent osteoporosis (bone loss).

Policy/Criteria

- I.** Most contracts require prior authorization approval of zoledronic acid prior to coverage. Zoledronic acid (Reclast) may be considered medically necessary for treatment of osteoporosis when an oral bisphosphonate (such as alendronate, ibandronate or risedronate) has not been tolerated or is contraindicated.

- II.** Administration and Authorization Period
 - A.** Regence does not consider zoledronic acid to be a self-administered medication.
 - B.** Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met.

Position Statement

Summary

- Osteoporosis is characterized by low bone mass and structural deterioration, leading to bone fragility and an increased risk of fractures of the hip, spine and wrist.^[7] The objective of osteoporosis treatment is to reduce the incidence of fractures.
- Generic alendronate provides the best value for the prevention and treatment of osteoporosis.
- There is no reliable evidence that one bisphosphonate is more effective for fracture prevention than another.
- There is no reliable evidence that one bisphosphonate is safer or better tolerated than another.
- There is no reliable comparative evidence to differentiate harms.
- All oral bisphosphonates carry some degree of risk of gastric irritation (oral formulations more so than injectables).

Clinical Efficacy

- There is evidence that alendronate (Fosamax), ibandronate (Boniva), risedronate (Actonel), and zoledronic acid (Reclast) decrease the risk of fracture.
- There are clinical trials of at least three years duration showing that alendronate (Fosamax[®]), risedronate (Actonel[®]), ibandronate (Boniva[®]), and zoledronic acid (Reclast) each reduce the risk of fracture in patients with osteoporosis. Fourteen to 23 patients need to be treated for 3 years to prevent one vertebral fracture. This is similar between the bisphosphonate medications.
- All fracture data for the oral bisphosphonates are based on the daily dosage form only. There are no fracture data for the weekly or monthly products or other modified dosing regimens.
- Bisphosphonates increase bone mineral density (BMD), which correlates to a decrease in the risk of fractures.
- There is no evidence that demonstrates superiority of any drug over another for the prevention of fractures. None of the head-to-head comparisons between agents had large enough sample sizes to detect differences.^[4]

Safety

- Side effects are similar for all oral bisphosphonate medications and include gastrointestinal problems such as difficulty swallowing, gastric ulcer and inflammation of the esophagus.^[4,17]
- Based on the FDA safety review regarding the possibility of an association between atrial fibrillation and bisphosphonate therapy the FDA states that healthcare professionals should not alter their prescribing patterns for bisphosphonates and patients should not stop taking their bisphosphonate medication.^[18]
- All of the bisphosphonates have extremely long presence in bone - years for oral, decades for IV zoledronic acid. The long term toxicity is unknown.
- Injectable products are options for patients with contraindications to the oral formulations, and are associated with fewer GI adverse events.
- There have been reports of osteonecrosis of the jaw (particularly following intravenous bisphosphonate treatment for patients with cancer). The level of risk for osteonecrosis in patients being treated for osteoporosis with bisphosphonates is not known, but appears extremely small for at least up to 5 years.^[17]

References

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| Cross References |
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| Actonel [®] , risedronate dru155 |
| Boniva [®] , ibandronate injection dru156 |
| Boniva [®] , ibandronate oral dru157 |
| Forteo [®] , teriparatide dru085 |

| Codes | Number | Description |
|--------------|---------------|--|
| HCPCS | J1740 | Injection, ibandronate sodium, 1 mg (Boniva 3 MG/3ML KIT) |
| HCPCS | J3488 | Injection, zoledronic acid (Reclast), 1 mg (Reclast 5 MG/100ML SOLN) |

Appendix 1: Indications for specified osteoporosis therapy

| | Alendronate | Risedronate | Ibandronate | Zoledronic acid |
|---|--------------------|--------------------|--------------------|------------------------|
| Postmenopausal Osteoporosis: Prevention | ✓ | ✓ | ✓ | ✓ |
| Postmenopausal Osteoporosis: Treatment | ✓ | ✓ | ✓ | ✓ |
| Glucocorticoid-Induced Osteoporosis: Prevention | - | ✓ | - | ✓ |
| Glucocorticoid-Induced Osteoporosis: Treatment | ✓ | ✓ | - | ✓ |
| Osteoporosis in Men | ✓ | ✓ | - | ✓ |
| Paget's disease | ✓ | ✓ | - | ✓ |

Appendix 2: Dosing regimens of bisphosphonate therapy

| Drug Products | Usual Dose/Route | Administration Considerations |
|--|---|---|
| alendronate (Fosamax [®]) ¹⁰ | <ul style="list-style-type: none"> • 5 mg p.o. daily • 10 mg p.o. daily • 35 mg p.o. weekly • 70 mg p.o. weekly • 40mg p.o. daily x 6mo | <ul style="list-style-type: none"> • Taken 30 minutes before first food, beverage, or medication • Swallowed with a full glass of water (180 to 240 mL). • Followed by at least 60 mL (one-fourth cup) of water • Do not lie down for at least 30 minutes and until after their first food of the day |
| ibandronate (Boniva [®]) ¹¹ | <ul style="list-style-type: none"> • 2.5 mg p.o. daily • 150 mg p.o. monthly • 3 mg IV every 3 months | <ul style="list-style-type: none"> • Taken 60 minutes before the first food or drink (other than water) • Swallowed whole with a full glass of plain water (180 to 240 mL; 6 to 8 oz) • Do not lie down for 60 minutes |
| risedronate (Actonel [®]) ⁹ | <ul style="list-style-type: none"> • 5 mg p.o. daily • 35 mg p.o. weekly • 30 mg p.o. daily x 2mo (Paget's) • 75 mg p.o. two consecutive days/month • 150mg p.o. monthly | <ul style="list-style-type: none"> • Taken 30 minutes before the first food or drink of the day other than water • Full glass of plain water (6 to 8 oz). • Do not lie down for 30 minutes |
| zoledronic acid injectable (Reclast [®]) ¹⁴ | <ul style="list-style-type: none"> • 5 mg IV once annually | <ul style="list-style-type: none"> • Given over no less than 15 minutes |