

## **RECLAST** (zoledronic acid)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Robert Sterling, MD Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

**RECLAST** is a bisphosphonic acid which inhibits osteoclastic bone resorption

**Authorization:** Treatment and prevention of osteoporosis in women in patients with GI intolerance to oral bisphosphanates; osteoporosis in men; glucocorticoid-induced osteoporosis in men or women\*; Paget's disease of bone\*\*

Unlabeled Uses: prevention of bone loss associated with aromatase inhibitor therapy in postmenopausal women with breast cancer; prevention of bone loss associated with androgen deprivation therapy in prostate cancer. (See VCHCP policy on Coverage of Prescription Medication of Off-Label Use.)

**Dosing:** 5 mg infusion (over no less than 15 minutes) once a year; earlier re-treatment may be considered in patients with Paget's disease who have clinically relapsed

**PRECAUTIONS:** Treat pre-existing hypocalcemia and treat patients with calcium (1200 mg) and vitamin D (800 IU) supplementation; contraindicated in patients with renal failure (CCr<35mL/min); osteonecrosis of the jaw (ONJ) after tooth extraction or dental abscess and atypical femoral fractures may occur (rare); musculoskeletal pain; acute transient inflammatory response at initiation of therapy; contraindicated in pregnancy

**DRUG INTERACTIONS:** Increased risk of GI ulcers and renal toxicity of NSAIDs; PPIs may decrease effectiveness; aminoglycoside and loop diuretics may increase the risk of hypocalcemia;

\* in a daily dosage equivalent to 7.5 mg or greater of prednisone and who are expected to remain on glucocorticoids for at least 12 months

\*\* with elevations in serum alkaline phosphatase of two times or higher than the upper limit of the age-specific normal

## REFERENCES

Bhalla AK, "Management of Osteoporosis in a Pre-menopausal Woman," *Best Pract Res Clin Rheumatol*, 2010, 24(3):313-27.

Black DM, Delmas PD, Eastell R, et al, "Once-Yearly Zoledronic Acid for Treatment of Postmenopausal Osteoporosis," *New Engl J Med*, 2007, 356(18):1809-22.

Brufsky AM, Harker WG, Beck JT, et al, "Final 5-year results of Z-FAST Trial: Adjuvant Zoledronic Acid Maintains Bone Mass in Postmenopausal Breast Cancer Patients Receiving Letrozole," *Cancer*, 2012, 118(5):1192-201.

Francini F, Pascucci A, Francini E, et al, "Osteonecrosis of the Jaw in Patients With Cancer Who Received Zoledronic Acid and Bevacizumab," *J Am Dent Assoc*, 2011, 142(5):506-13

Hershman DL, McMahon DJ, Crew KD, et al, "Prevention of Bone Loss By Zoledronic Acid in Premenopausal Women Undergoing Adjuvant Chemotherapy Persist Up to One Year Following Discontinuing Treatment," *J Clin Endocrinol Metab*, 2010, 95(2):559-66

National Osteoporosis Foundation (NOF), "Clinician's Guide to Prevention and Treatment of Osteoporosis," Washington, DC, 2013. Available at http://www.nof.org/files/nof/public/content/resource/913/files/580.pdf

Sellmeyer DE, "Atypical Fractures as a Potential Complication of Long-term Bisphosphonate Therapy," *JAMA*, 2010, 304(13):1480-4.

## **Revision History:**

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