

Origination Date: 4/08	Revision Date(s): 4/09
Developed By: Medical Criteria Committee	

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Date: 04/23/09

Description:

Zoledronic acid belongs to a class of medications called bisphosphonates. Its principal pharmacologic action is inhibition of bone resorption. It works by slowing bone breakdown and decreasing the amount of calcium released from the bones into the blood.

Zoledronic acid is administered intravenously and is available under the brand names Zometa and Reclast. Reclast is a single-dose infusion that is given once a year while Zometa may be given more than one time per year if needed.

Criteria:

- I. ODS will cover zoledronic acid (Zometa, Reclast) to plan limitation for **any** of the following indications:
 - A. The patient is a postmenopausal female with a diagnosis of osteoporosis, defined as a bone mineral density test T-score of -2.5 or more standard deviations below the young adult mean value. The patient has also tried oral bisphosphonate for 6 months and has documented treatment failure or intolerance; **or**
 - B. The patient has a diagnosis of Paget's disease and has an elevation of serum alkaline phosphatase two times or higher than the upper limit of the age-specific normal reference range or is symptomatic and at risk for complications from their disease; **or**
 - C. Hypercalcemia of malignancy; **or**
 - D. Multiple myeloma; **or**
 - E. Prophylaxis of drug-induced osteopenia secondary to androgen deprivation therapy in prostate cancer; **or**
 - F. Bone metastases or bone pain presumed due to bone metastases from prostate cancer, lung cancer, breast cancer, or other solid tumor types. For treatment of bone metastasis from prostate cancer, the patient must have cancer progression after treatment with at least one hormonal therapy

Information to be Submitted with Pre-Authorization Request:

- Chart notes from the treating provider documenting patient condition and treatment tried.

Applicable CPT/HCPC:

Note: this list may not be all inclusive

J3487	Injection, zoledronic acid (Zometa), 1 mg
J3488	Injection, zoledronic acid (Reclast), 1 mg

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References:

- Black D, Delmas P, Eastell R, et al. Once-yearly zoledronic acid for treatment of postmenopausal osteoporosis. *New Eng J Med.* 2007 May;18(356):1809-1822.
- Reid I, Brown J, Burckhardt P, et al. Intravenous zoledronic acid in postmenopausal women with low bone mineral density. *New Eng J Med.* 2002 Feb;9(346):653-661.
- Reed SD, Radeva JI, Glendenning GA, et al. Cost-effectiveness of zoledronic acid for the prevention of skeletal complications in patients with prostate cancer. *J Urol.* 2004 Apr;171(4):1537-42.
- Drug Information: Zoledronic Acid Injection. Medline Plus. Accessed on April 11, 2008. Available at URL address: <http://www.nlm.nih.gov/medlineplus/print/druginfo/medmaster/a605023.html>
- Neville-Webbe H, Coleman RE. The use of zoledronic acid in the management of metastatic bone disease and hypercalcaemia. *Palliat Med.* 2003 Sep;17(6):539-53.
- Wellington K, Goa KL. Zoledronic acid: a review of its use in the management of bone metastases and hypercalcaemia of malignancy. *Drugs.* 2003;63(4):417-37.
- Perry CM, Figgitt DP. Zoledronic acid: a review of its use in patients with advanced cancer. *Drugs.* 2004;64(11):1197-211.
- Physician Advisors