

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

Neal Mills MD MBA

Approve:

Neal Mills MD. MBA

Date: 3/15/2011

ODS Rx ^{1.0} <input type="checkbox"/>	ODS Rx ^{2.0} <input checked="" type="checkbox"/>	OEBB <input checked="" type="checkbox"/>	OHP <input type="checkbox"/>
NON-SPECIALTY <input type="checkbox"/>	SPECIALTY <input checked="" type="checkbox"/>		
PA <input checked="" type="checkbox"/>	QLL <input type="checkbox"/>	STEP THERAPY <input type="checkbox"/>	

Zoledronic Acid

Generic Name (Brand): Zoledronic Acid (Reclast, Zometa)

GUIDELINES FOR USE

1. What is the patient's diagnosis?
If the diagnosis is an FDA approved indication, continue to #2.
If not, do not approve.
2. What is the treatment dose?
If treatment dose is within the approved dosing range, continue to #3.
If not, do not approve.
3. What clinical parameters will be monitored to establish treatment effectiveness?
If submitted monitoring plan is consistent with effectiveness monitoring, continue to #4.
If not, do not approve.
4. **Approve for 6 months.**

FDA APPROVED INDICATIONS

Zometa:

Hypercalcemia of malignancy: For the treatment of hypercalcemia of malignancy. The safety and efficacy of zoledronic acid in the treatment of hypercalcemia associated with hyperparathyroidism or with other non-tumor-related conditions have not been established.

Multiple myeloma and bone metastases from solid tumors: For the treatment of 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 1 hormonal therapy.

Reclast:

Paget disease: For the treatment of Paget disease of bone in men and women. Treatment is indicated in patients with Paget disease of bone with elevations in serum alkaline phosphatase

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of 2 times or higher than the upper limit of the age-specific normal reference range, or those who are symptomatic, or those at risk for complications from their disease, to induce remission (normalization of serum alkaline phosphatase).

Postmenopausal osteoporosis: For treatment of osteoporosis in postmenopausal women. In postmenopausal women with osteoporosis, zoledronic acid reduces the incidence of fractures (eg, hip, vertebral, nonvertebral osteoporosis-related fractures).

TREATMENT DOSE / DURATION / REGIMEN

Zometa:

Hypercalcemia of malignancy: Consider the severity of, as well as the symptoms of, tumor-induced hypercalcemia when considering use of zoledronic acid for injection. Vigorous saline hydration alone may be sufficient to treat mild, asymptomatic hypercalcemia.

Dose: The maximum recommended dose of zoledronic acid in hypercalcemia of malignancy (albumin-corrected serum calcium is at least 12 mg/dL [3 mmol/L]) is 4 mg. Albumin-corrected serum calcium (C_{ca}, mg/dL) = Ca + 0.8 (mid-range albumin-measured albumin in mg/dL). The 4 mg dose must be given as a single-dose intravenous (IV) infusion over no less than 15 minutes.

Hydration: Adequately rehydrate patients prior to administration of zoledronic acid. Promptly initiate vigorous saline hydration, an integral part of hypercalcemia therapy, and make an attempt to restore the urine output to about 2 L/day throughout treatment. Mild or asymptomatic hypercalcemia may be treated with conservative measures (eg, saline hydration, with or without loop diuretics). Adequately hydrate patients throughout the treatment, but overhydration, especially in those patients who have cardiac failure, must be avoided. Do not employ diuretic therapy prior to correction of hypovolemia.

Re-treatment: Re-treatment with zoledronic acid 4 mg may be considered if serum calcium does not return to normal or remain normal after initial treatment. It is recommended that a minimum of 7 days elapse before re-treatment to allow for full response to the initial dose. Renal function must be carefully monitored in all patients receiving zoledronic acid, and possible deterioration in renal function must be assessed prior to re-treatment with zoledronic acid.

Multiple myeloma and bone metastases from solid tumors: The recommended dose of zoledronic acid in patients with multiple myeloma and metastatic bone lesions from solid tumors for patients with creatinine clearance (CrCl) greater than 60 mL/min is 4 mg infused over no less than 15 minutes every 3 or 4 weeks. The optimal duration of therapy is not known.

Calcium/Vitamin D supplementation: Administer patients an oral calcium supplement of 500 mg and a multiple vitamin containing 400 units of vitamin D daily.

EFFECTIVENESS MONITORING PARAMETERS

Clinical and laboratory response including serum calcium levels.

REFERENCES

Product Information.

Facts and Comparisons 4.0. Accessed 09/15/08.

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Reviewed; 2/23/11

Recommendations

- T-score < -2.5
- Trial and failure of oral bisphosphonates
- CrCL 60ml/mn