

Prior Authorization DRUG Guidelines

BONIVA (ibandronate sodium)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Robert Sterling, MD

Last Approval Date: 1/27/15, 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Boniva is a bisphosphonate that inhibits osteoclast-mediated bone resorption, reducing bone turnover, thus leading to an average net gain in bone mass

Pre-Authorization Criteria: Prevention or treatment of osteoporosis in postmenopausal women when unable to tolerate or failed treatment with alendronate or risendronate.

Off-Label Uses: hypercalcemia of malignancy; treatment to reduce bone pain and skeletal complications from metastatic bone disease due to breast cancer. (See VCHCP policy on Coverage of Prescription Medication for Off-Label Use.)

Dosing: One 150mg tablet taken once monthly on the same date each month

PRECAUTIONS: gastrointestinal irritation; hypocalcemia; musculoskeletal pain; post dental extraction osteonecrosis; occult atypical fractures of the femur

Note: 1) All patients on bisphosphonate therapy should have the need for continued therapy re-evaluated on a periodic basis. Patients at low-risk for fracture should be considered for drug discontinuation after 3 to 5 years of use. Patients who discontinue therapy should have their risk for fracture re-evaluated periodically. 2) Treat hypocalcemia and other disturbances of bone and mineral metabolism before starting BONIVA therapy. Instruct patients to take supplemental calcium and vitamin D if their dietary intake is inadequate. 3) Any patient with a history of bisphosphonate exposure who presents with thigh or groin pain should be suspected of having an atypical fracture and should be evaluated to rule out an incomplete femur fracture.

DRUG INTERACTIONS: increased risk and/or severity of gastrointestinal irritation with concomitant use of aspirin/NSAIDs or other medications which may cause GI upset; calcium, magnesium or iron supplements interfere with absorption of **Boniva** (take with an interval of 1-2 hours);

REFERENCES

Barrett J, Worth E, Bauss F, et al, "Ibandronate: A Clinical Pharmacological and Pharmacokinetic Update," *J Clin Pharmacol*, 2004, 44(9):951-65.

Edwards BJ, Hellstein JW, Jacobsen PL, et al, "Updated Recommendations for Managing the Care of Patients Receiving Oral Bisphosphonate Therapy: An Advisory Statement From the American Dental Association Council on Scientific Affairs," *J Am Dent Assoc*, 2008, 139(12):1674-7.

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>

Pereira RM, Carvalho JF, Paula AP, et al, "Guidelines for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis," *Rev Bras Reumatol*, 2012, 52(4):580-93.

von Moos R, "Bisphosphonate Treatment Recommendations for Oncologists," *Oncologist*, 2005, 10 (Suppl 1):19-24.

Assael LA, "Oral Bisphosphonates as a Cause of Bisphosphonate-Related Osteonecrosis of the Jaws: Clinical Findings, Assessment of Risks, and Preventive Strategies," *J Oral Maxillofac Surg*, 2009, 67(5 Suppl):35-43.

American Dental Association Council on Scientific Affairs, "Dental Management of Patients Receiving Oral Bisphosphonate Therapy: Expert Panel Recommendations," *J Am Dent Assoc*, 2006, 137(8):1144-50. Available at <http://jada.ada.org/cgi/content/full/137/8/1144>

Revision History:

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD

Date Approved by P&T Committee: 1/27/15

Date Reviewed/Updated: 2/5/15 by C. Sanders, MD; R. Sterling, MD

S:\2019\DRUGS POLICIES\VCHCP

Date Approved by P&T Committee: 1/26/16

Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/24/17

Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/23/18

Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – check ESI