

Zometa[®] (zoledronic acid) Injection J3489



When requesting Zometa[®] (zoledronic acid), the individual requiring treatment must be diagnosed with the following FDA-approved indications or approved compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications^{1,6}

- Hypercalcemia of malignancy¹
- Multiple myeloma¹
- Bone metastases from solid tumors^{1,3}

Approved Off-label Compendial uses

- Breast cancer: for prevention of skeletal-related events in an individual with bone metastases and an expected survival of ≥ 3 months³
- Prostate cancer: for prevention of skeletal-related events in men with castration-recurrent disease who have bone metastases³
- Prevention or treatment of osteoporosis in men with prostate cancer²⁻⁴
- To reduce the risk of fractures and improve bone mineral density in postmenopausal (natural or induced) women with breast cancer receiving adjuvant endocrine therapy³

Coverage Guidelines

For all indications, the individual meets the following safety criteria for approval:

- The individual has a serum calcium or corrected calcium greater than the lower limit of normal per laboratory reference.¹
- Does not have severe renal impairment¹

Hypercalcemia of malignancy¹

- The individual's albumin-corrected calcium* is ≥ 12 mg/dL¹
- For initial treatment:
 - Approve for a single dose¹
- For retreatment:¹
 - The individual's serum calcium level has not returned to normal or does not remain normal after initial treatment¹
 - Zometa[®] (zoledronic acid) will be given ≥ 7 days after the initial dose¹
 - Approve for a single dose¹

Multiple myeloma¹

- Zometa[®] (zoledronic acid) will be used in conjunction with standard antineoplastic therapy¹

Bone metastases from a solid tumor

- Zometa[®] (zoledronic acid) will be used in conjunction with standard antineoplastic therapy³
 - If the primary cancer diagnosis is breast cancer, then the individual has an expected survival of 3 months or greater³
 - If the primary cancer diagnosis is prostate cancer, then the individual has a castration-recurrent disease³

Prevention or treatment of osteoporosis in men with prostate cancer²⁻⁴

- The individual is at high risk for fracture, defined as:
 - Baseline bone mineral density (BMD) T-score by DXA less than or equal to -2.5⁵
 - History of an osteoporotic (fragility) fracture⁵
 - Baseline BMD T-score by DXA between -1 and -2.5 if the FRAX[®] 10-year fracture probability for major osteoporotic fracture is $\geq 20\%$ or the 10-year probability of hip fracture is $\geq 3\%$ ⁵
- The individual is receiving androgen deprivation therapy²⁻⁴

To reduce the risk of fractures and improve BMD in postmenopausal (natural or induced) women with breast cancer³

- The individual is at high risk for fracture, defined as:
 - Baseline BMD T-score by DXA less than or equal to -2.5⁵
 - History of an osteoporotic (fragility) fracture⁵
 - Baseline BMD T-score by DXA between -1 and -2.5 if the FRAX[®] 10-year fracture probability for major osteoporotic fracture is $\geq 20\%$ or the 10-year probability of hip fracture is $\geq 3\%$ ⁵
- The individual is receiving adjuvant endocrine therapy³

*Albumin-corrected Ca in mg/dL = Ca in mg/dL + 0.8 (4 g/dL - individual albumin [g/dL])

Approval duration is 12 months

Additional Information for Prescribers¹

- Hypocalcemia should be corrected before initiating Zometa[®] (zoledronic acid). Adequately supplement with calcium and vitamin D. Monitor serum calcium closely with concurrent use of other drugs known to cause hypocalcemia to avoid severe or life-threatening hypocalcemia.
- Renal toxicity may be greater in individuals with renal impairment. Do not use doses greater than 4 mg. Treatment in individuals with severe renal impairment is not recommended. Monitor serum creatinine before each dose.

References

1. Zometa prescribing information. Stein, Switzerland: Novartis Pharma Stein AG: December 2016. <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/Zometa.pdf>. Accessed April 14, 2017.
2. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed April 14, 2017. <http://www.nlm.nih.gov/research/umls/sourcereleasedocs/2010AA/MMX/>.
3. National Comprehensive Cancer Network. NCCN drugs and biologics compendium. http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 14, 2017.
4. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2017. Prostate Cancer. Accessed April 14, 2017. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Prostate Cancer 2.2017. ©2017 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org.
5. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4176573/pdf/198_2014_Article_2794.pdf. Accessed March 24, 2017.

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