



Comprehensive Cancer Center

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Date of request: 1/15/2016

NCCN Guidelines Panel: Breast Cancer

On behalf of Sylvester Comprehensive Cancer Center, I respectfully request the NCCN Breast Cancer Panel to review the enclosed data for inclusion of Breast Cancer as an indication in the adjuvant setting for Zoledronic Acid (Zometa).

Specific Changes: Recommend the use of Zoledronic Acid (Zometa) in the adjuvant setting in the treatment of breast cancer.

FDA Clearance: Zometa® (zoledronic acid for injection) is indicated for the treatment of hypercalcemia of malignancy and Osetolytic, Osetoblastic and Mixed Bone Metastases of Solid Tumor and Osetolytic Lesions of Multiple Myeloma. It is not currently FDA recommended for the treatment of Breast Cancer.

Rationale: Adjuvant bisphosphonate treatment in early breast cancer: meta-analysis from randomized trials (Lancet 2015 386:1353-61) shows a significant reduction in recurrence, distant recurrence, bone recurrence and breast cancer mortality. Due to the literature showing that adjuvant bisphosphonates reduce the rate of breast cancer recurrence in the bone and improve breast cancer survival, we request the inclusion of Breast Cancer to the NCCN Compendium for Zoledronic Acid (Zometa).

The following articles are submitted in support of this proposed change:

- 1) ABCSG-12 published in New England Journal of Medicine 2009; 360: 679.

This article demonstrated an improvement in Disease Free Survival in premenopausal women who underwent ovarian suppression with Zoladex and received adjuvant hormonal therapy with either tamoxifen or aromatase inhibitor.

- 2) Bone sub-study was published in Lancet Oncology 2008; 9:840

This article showed that Zometa preserved bone density and prevented osteoporosis in women undergoing breast cancer therapy.

- 3) Adjuvant bisphosphonate treatment in early breast cancer: meta-analysis from randomized trials (Lancet 2015 386:1353-61)

This study presented data on 18,766 women from trials of 2-5 years of bisphosphonate with median follow-up of 5-6 years. While there was no apparent effect on premenopausal women, among 11,767 postmenopausal women there was a significant reduction in recurrence, distant recurrence, bone recurrence and breast cancer mortality.

Sincerely,

Dr. Stephen Richman



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Leading the Search for a Cancer Cure