BC Cancer Protocol Summary for Adjuvant Therapy for Breast Cancer in Post-menopausal Women Using Pamidronate

Protocol Code	*BRAJPAM*
Tumour Group	*Breast*
Contact Physician	*Dr. Sophie Sun*

ELIGIBILITY:

- postmenopausal (including women with chemically induced menopause with LHRH agonists)
- Stage II or III only (pT2-4 pN0-3; pT0-4pN1-3), or post neo-adjuvant chemotherapy stage ypT2-4 ypN0-3; ypT0-4 ypN1-3
- Adequate renal function (CrCl greater than or equal to 30 mL/min)
- Demonstrated intolerance to zoledronic acid
- Bisphosphonate therapy must begin within 1 year of diagnosis

TESTS:

- Completion of necessary dental work is recommended prior to starting pamidronate
- Baseline and prior to each treatment: serum creatinine
- If clinically indicated: serum calcium* and albumin (or ionized calcium)

  *corrected calcium (mmol/L) = total calcium (mmol/L) + (0.02 x [40 – albumin in g/L])

PREMEDICATIONS:

- None

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
pamidronate	90 mg	IV in 250 mL NS over 1 hour

- Repeat once every 24 weeks for up to 5 years. For scheduling purpose, the treatment day can be up to +/- 2-4 weeks for the next treatment cycle.
- If patient is on adjuvant chemotherapy, pamidronate is usually started after completion of chemotherapy treatment course.

DOSE MODIFICATIONS:

1. **Renal dysfunction:**
   - There is limited experience with pamidronate in patients with serum creatinine greater than 440 micromol/L or a creatinine clearance less than 30 ml/minute. For patients who show evidence of deterioration in renal function while on pamidronate, treatment should be withheld until renal function returns to within 10% of baseline value. Renal deterioration is defined as follows:

   -patients with a normal baseline creatinine: increase of 44.2 micromol/L

   -patients with an abnormal baseline creatinine: increase of 88.4 micromol/L

PRECAUTIONS:

1. Pamidronate should not be given as a bolus due to severe local reactions and thrombophlebitis.
2. **Symptomatic hypocalcemia** (e.g., muscle spasms, irritability) may occur and may require calcium supplement. Avoid concomitant use of other calcium lowering agents such as corticosteroids and loop diuretics.
3. After the use of bisphosphonates, there is a persistent risk of jaw osteonecrosis. Patients in whom bisphosphonates are planned should have prophylactic assessment and management by a dentist and all later dental work should be undertaken cautiously by dental specialists experienced in the recognition and management of jaw osteonecrosis

Call Dr. Sophie Sun or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

References:

1. Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Adjuvant bisphosphonate treatment in early breast cancer: meta-analyses of individual patient data from randomised trials. Lancet 2015;386(10001):1353-61. Erratum in: Lancet 2016;387(10013):30.
2. Ben-Aharon I, Vidal L, Rizel S, et al. Bisphosphonates in the adjuvant setting of breast cancer therapy--effect on survival: a systematic review and meta-analysis. PLoS One 2013 Aug 26;8(8):e70044.
3. Pfizer Canada. Pamidronate disodium product monograph. Kirkland, Quebec. 11 December 2018