

# BCCA Protocol Summary for **Neoadjuvant or Adjuvant Therapy** for Breast Cancer using Letrozole in Postmenopausal Women

**Protocol Code**

*BRAJLET*

**Tumour Group**

*Breast*

**Contact Physician**

*Dr. Susan Ellard*

## **ELIGIBILITY:**

- May be given preoperatively in postmenopausal women with hormone receptor positive breast cancer who are unsuitable for immediate surgery or preoperative chemotherapy
- Only for postmenopausal women (no menses for greater than 12 months; check FSH, LH, estradiol levels if less than 55 and prior hysterectomy or uncertain menopausal status due to young age or other factors) with hormone receptor positive invasive breast cancer for the following indications:
- Upfront use for 5 years: at high risk of early relapse:
  - High grade and/or
  - Low ER (1+) and/or
  - Stage III (includes any N2/N3, T4 or T3N+)
- Early switch: Following 2 to 3 years of adjuvant Tamoxifen (early switch) to complete 5 years of hormone blockade (except T1N0 low grade disease)
- Late switch: Following 4.5 to 6 years of adjuvant Tamoxifen, remaining free of relapse, within less than 12 months of end of tamoxifen therapy (except T1N0 low grade); approved for up to 5 additional years of letrozole blockade (Note: patients who started with letrozole but had to switch to another aromatase inhibitors due to side effects may also continue to 5 years only with CAP approval)
- Contraindications to Tamoxifen or intolerant of Tamoxifen

See Cancer Management [Guidelines](#) for [current guidelines](#).

## **EXCLUSIONS:**

- premenopausal women
- DCIS only
- T1N0 low grade disease (use BRAJTAM alone unless intolerant or contraindicated)

## **TESTS**

Baseline: bone density before or after 2 to 3 month trial of therapy

Biannual: bone density

If clinically indicated: serum cholesterol, triglycerides

## TREATMENT:

### Upfront Therapy:

letrozole 2.5 mg PO daily x 5 years

### Early Switch following 2 to 3 years of tamoxifen:

letrozole 2.5 mg PO daily x 3 to 2 years **(total treatment time of 5 years)**

### Late Switch following 4.5 to 6 years of tamoxifen

letrozole 2.5 mg PO x 5 years

## PRECAUTIONS:

1. Hepatic dysfunction: Aromatase inhibitors are considered safe in mild-to-moderate hepatic dysfunction but have not been studied in severe hepatic dysfunction.
2. Bone density: The long-term effects of aromatase inhibitors on bone density in adjuvant therapy patients are unknown. Supplementation with calcium and vitamin D and regular weight bearing exercise is recommended. A bisphosphonate should be considered if clinically indicated. Caution in patients with an already established diagnosis of clinically significant osteoporosis.
3. Hyperlipidemia: An increase in cholesterol or triglyceride levels may occur when an aromatase inhibitor is initiated. Levels may need to be checked during the first few months of therapy, especially in those patients with prior significant lipid elevations.

**Contact Dr. Susan Ellard or tumour group delegate at (250) 712-3900 or 1-888-563-7773 with any problems or questions regarding this treatment program.**

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Date Revised: 01 July 2015 (Title and Eligibility clarified)

## References<sup>1-6</sup>

1. Coombes RC, Hall E, Gibson LJ, et al. A randomized trial of exemestane after two to three years of tamoxifen therapy in postmenopausal women with primary breast cancer. N Engl J Med 2004;350(11):1081-92.
2. The ATAC Trialists' Group. Anastrozole Alone or in Combination with Tamoxifen Alone for Adjuvant Treatment of Postmenopausal Women with Early-Stage Breast Cancer. Cancer 2003;98:1802-10.
3. The ATAC Trialists' Group. Anastrozole alone or in combination with tamoxifen versus tamoxifen alone for adjuvant treatment of postmenopausal women with early breast cancer: first results of the ATAC randomised trial. Lancet 2002;359(9324):2131-39.
4. The ATAC Trialists' Group. Results of the ATAC (Arimidex, Tamoxifen, alone or in combination) trial after completion of 5 years' adjuvant treatment for breast cancer. Lancet Published online December 8, 2004;364(9451).
5. Winer EP, Hudis C, Burstein HJ, et al. American Society of Clinical Oncology technology assessment on the use of aromatase inhibitors as adjuvant therapy for postmenopausal women with hormone receptor-positive breast cancer: status report 2004. J Clin Oncol 2005;23(3):619-29.
6. Goss PE, Ingle JN, Martino S, et al. A randomized trial of letrozole in postmenopausal women after five years of tamoxifen therapy for early-stage breast cancer. N Engl J Med 2003;349(19):1793-802.