

BCCA Protocol Summary for Adjuvant Therapy for Breast Cancer using Letrozole in Postmenopausal Women

Protocol Code

BRAJLET

Tumour Group

Breast

Contact Physician

Dr. Susan Ellard

ELIGIBILITY:

- 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 2-3 years of adjuvant Tamoxifen (early switch) to complete 5 years of hormone blockade (except T1N0 low grade disease)
- Late switch: Following 4.5-6 years of adjuvant Tamoxifen, remaining free of relapse, within **less than** 12 months of end of tamoxifen therapy (except T1N0 low grade); currently approved for up to 3 additional years of hormone blockade
- Contraindications to Tamoxifen or intolerant of Tamoxifen

See Cancer Management Manual 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 2-3 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 2-3 years of [tamoxifen](#):

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

Late Switch following 4.5-6 years of tamoxifen

Letrozole 2.5 mg PO x 3 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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References¹⁻⁶

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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.