BC Cancer Protocol Summary for Neoadjuvant or Adjuvant Therapy for Breast Cancer Using Tamoxifen

Protocol Code	*BRAJTAM*
Tumour Group	*Breast*
Contact Physicians	*Dr. Susan Ellard* *Dr. Nathalie LeVasseur*

ELIGIBILITY:

- May be given preoperatively in hormone receptor positive breast cancer patients who are unsuitable for immediate surgery or preoperative chemotherapy
- Adjuvant hormonal treatment for breast cancer, initiated up to 10 years after diagnosis and treatment
  - All premenopausal hormone receptor-positive women: upfront tamoxifen for up to a total of 10 years only
- Options for postmenopausal hormone receptor positive invasive breast cancer:
  - Upfront tamoxifen for up to a total of 10 years only
    - Consider aromatase inhibitor options below if disease higher than T1N0 low grade tumours
    - Any postmenopausal hormone receptor positive invasive breast cancer in patients intolerant to aromatase inhibitors
  - Early switch: 2 to 3 years of adjuvant tamoxifen to begin 5 to 10 years of hormone blockade (except T1N0 low grade disease)
  - Late switch: 5 years of adjuvant tamoxifen, followed by up to 5 additional years of aromatase inhibitor (except T1N0 low grade)
- See Cancer Management Guidelines for current guidelines.

Notes:

- Patients with microinvasive ductal carcinoma in situ (DCIS) are eligible for either BRAJLDTAM or BRAJTAM per provider discretion
- Patients who decline adjuvant radiation for DCIS are eligible for BRAJTAM
- Patients with low risk DCIS are eligible for low dose tamoxifen (see BRAJLDTAM)

EXCLUSIONS:

- Hormone receptor-negative
- Patients with a history of significant thromboembolic disease

CAUTION:

- Advanced liver disease

Warning: The information contained in these documents are a statement of consensus of BC Cancer professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is at your own risk and is subject to BC Cancer's terms of use available at www.bccancer.bc.ca/terms-of-use

TESTS:

- If clinically indicated (see PRECAUTIONS, below): CBC & Diff, platelets, serum cholesterol and triglycerides, total bilirubin, alkaline phosphatase, ALT, GGT, ophthalmologic exam

TREATMENT:

Upfront:
tamoxifen 20 mg PO daily x up to a total of 10 years

Early Switch:
tamoxifen 20 mg PO daily x 2 to 3 years, followed by aromatase inhibitor to complete up to a total of 10 years (see BRAJANAS, BRAJEXE, or BRAJLET)

Late Switch:
tamoxifen 20 mg PO daily x 5 years, followed by aromatase inhibitor x 2 to 5 years (see BRAJANAS, BRAJEXE, or BRAJLET)

MODIFICATIONS:

1. Intolerant or serious complications during tamoxifen therapy
   - Post-menopausal patients may be switched to aromatase inhibitor to complete adjuvant hormonal therapy (see BRAJANAS, BRAJEXE, BRAJLET)

PRECAUTIONS:

1. **Myelosuppression:** Mild myelosuppression with transient thrombocytopenia may occur rarely. The association with tamoxifen is uncertain.
2. **Endometrial Cancer:** Pelvic complaints such as unusual vaginal bleeding or intermenstrual spotting require prompt evaluation.
3. **Ocular Toxicity:** Ocular toxicity is rare and may occur after only a few weeks of therapy, although it is more common with prolonged treatment. Ophthalmologic examination is recommended if visual disturbances occur.
4. **Thromboembolism:** Tamoxifen is associated with an increased risk of thromboembolism that is comparable to estrogen replacement therapy.
5. **Hepatotoxicity:** While hepatotoxicity is rare and usually presents as elevated hepatic enzymes, more serious liver abnormalities have been reported.
6. **Ovulation Induction:** Tamoxifen may induce ovulation in pre- and peri-menopausal women. Barrier forms of contraception are highly recommended. Women should not become pregnant while taking tamoxifen, as there is positive evidence of human fetal risk.
7. **Hyperlipidemia:** Elevations in cholesterol and triglycerides may occur in patients with pre-existing hyperlipidemias.

Call Dr. Nathalie LeVasseur or tumour group delegate at (604) 930-2098 or 1-800-663-3333 with any problems or questions regarding this treatment program.

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3. Coombes, RC 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
4. 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):1793-02.
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