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

Protocol Code  
BRAJTAM

Tumour Group  
Breast

Contact Physician  
Dr. Susan Ellard

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 (eligible if completed 5 yrs of therapy within last 12 months)
  - Options for postmenopausal hormone receptor positive invasive breast cancer:
    - Upfront tamoxifen for up to a total of 10 years only (eligible if completed 5 yrs of therapy within last 12 months)
      - Consider aromatase inhibitor (AI) 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: 2-3 years of adjuvant Tamoxifen to begin 5 years of hormone blockade (except T1N0 low grade disease)
    - Late switch: 5 years of adjuvant Tamoxifen, followed by up to 5 additional years of letrozole, or 3 additional years of anastrozole or exemestane (except T1N0 low grade) Note: patients who started on letrozole but had to switch to another aromatase inhibitor due to side effects may also continue to 5 years with CAP approval only

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

TESTS:
- Annually: gynecological exam (postmenopausal patients with an intact uterus)
- If clinically indicated (see PRECAUTIONS, below): CBC and diff, platelets, serum cholesterol and triglycerides, liver enzymes and bilirubin, 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 2-3 years, followed by BRAJANAS, BRAJEXE, or BRAJLET for a total treatment time of 5 years.

Late Switch:
tamoxifen 20 mg PO daily x 5 years, followed by BRAJANAS, BRAJEXE, or BRAJLET for a further 3 years of treatment (up to 5 years if letrozole – see BRAJLET)

MODIFICATIONS:
1. Intolerant or serious complications during tamoxifen therapy
   - Post-menopausal patients may be switched to BRAJANAS, BRAJEXE, BRAJLET for a total of 5 years of adjuvant hormonal therapy

PRECAUTIONS:
1. Myelosuppression: Mild myelosuppression with transient thrombocytopenia may occur rarely. The association with tamoxifen is uncertain.
2. Endometrial Cancer: Annual gynecological examinations are recommended. Pelvic complaints, such as unusual vaginal bleeding, 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 recommended.
7. Hyperlipidemia: Elevations in cholesterol and triglycerides may occur in patients with pre-existing hyperlipidemias.

Call 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.

Date activated: N/A
Date revised: 1 Nov 2016 (Eligibility clarified)
References: