BCCA Protocol Summary for Adjuvant Therapy for Breast Cancer using DOXOrubicin and Cyclophosphamide

Protocol Code BRAJAC

Tumour Group Breast

Contact Physician Dr. Nathalie Levasseur

ELIGIBILITY:

Patient must have:

high-risk breast cancer without systemic metastases

Note:

- Primary prophylaxis with G-CSF is not mandatory, but may be considered if patient has one or more of the following risk factors:
 - Prior chemotherapy or radiation therapy
 - Persistent neutropenia
 - Recent surgery and/or open wounds
 - Liver dysfunction
 - Renal dysfunction
 - Older than 65 years of age and receiving full chemotherapy dose intensity

TESTS:

- Baseline: CBC & Diff, total bilirubin
- Baseline, if clinically indicated: ALT, LDH
- Before each treatment: CBC & Diff
- If clinically indicated: total bilirubin, ALT, LDH, creatinine

PREMEDICATIONS:

Antiemetic protocol for highly emetogenic chemotherapy (see protocol SCNAUSEA)

TREATMENT:

Drug	Dose	BCCA Administration Guideline
DOXOrubicin (ADRIAMYCIN®)	60 mg/m ²	IV push
cyclophosphamide	600 mg/m ²	IV in NS or D5W 100 to 250 mL over 20 min to 1 hour

- Repeat every 21 days x 4 cycles.
- If radiation therapy is required, it is given following completion of chemotherapy (BCCA Cancer Management Manual).

DOSE MODIFICATIONS:

1. Hematological:

ANC (x 109/L)	Platelets (x 10 ⁹ /L)	Dose (both drugs)
Greater than or equal to 1.5	Greater than or equal to 90	100%
1.0 to 1.49	70 to 89	75%
Less than 1.0	Less than 70	delay

- 2. **Hepatic dysfunction:** Dose modification required for DOXOrubicin (see <u>BCCA Cancer Drug Manual</u>).
- 3. **Renal dysfunction:** Dose modification may be required for cyclophosphamide (see BCCA Cancer Drug Manual).

PRECAUTIONS:

- 1. **Cardiac Toxicity**: DOXOrubicin is cardiotoxic and must be used with caution, if at all, in patients with severe hypertension or cardiac dysfunction. Cardiac assessment recommended if lifelong dose of 400 mg/m² to be exceeded (see BCCA Cancer Drug Manual).
- 2. **Extravasation:** DOXOrubicin causes pain and tissue necrosis if extravasated. Refer to BCCA Extravasation Guidelines.
- 3. Febrile Neutropenia: Risk of febrile neutropenia is 10 to 20%. If a patient has additional risk factors outlined in Eligibility Note above, risk of febrile neutropenia may be considered to be greater than 20%; consider prophylactic filgrastim per discretion of the treating physician. Febrile neutropenia can result in serious patient harm, treatment delays, and hospitalization. Fever or other evidence of infection must be assessed promptly and treated aggressively.

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

Date Revised: 1 May 2025 (Contact physician, eligibility, tests and precautions updated)

Reference:

Fisher B, Brown AM, Dimitrov NV, et al. Two months of doxorubicin-cyclophosphamide with and without interval reinduction therapy compared with 6 months of cyclophosphamide, methotrexate and fluorouracil in positive-node breast cancer patients with tamoxifen-nonresponsive tumors: results from the National Surgical Adjuvant Breast and Bowel Project B-15. J Clin Oncol 1990;8(9):1483-96.