BC Cancer Protocol Summary for Palliative Therapy for Metastatic Breast Cancer using Weekly DOCEtaxel

Protocol Code:	*BRAVDOC7*
Tumour Group:	*Breast*
Contact Physician:	*Dr. Karen Gelmon*

ELIGIBILITY:

- First, second, or third line treatment of metastatic breast cancer patients with ECOG performance status 0, 1, or 2, and greater than 3 month life expectancy
- Poor tolerance to high doses of dexamethasone used for BRAVDOC
- Patients unable to tolerate BRAVDOC
- For other indications, or for more than 4 cycles, a BC Cancer "Compassionate Access Program" request must be approved.

TESTS:

- Baseline: CBC & diff, platelets, ALT, Alk Phos, LDH, GGT
- Before each treatment: CBC & diff, platelets
- Before Cycle 3 and any time if clinically indicated*: Bilirubin, Alk Phos, ALT, GGT

See Precaution #5 for guidelines regarding hepatic dysfunction

PRE & POST MEDICATIONS:

- dexamethasone 8 mg PO 1 hour prior to DOCEtaxel treatment
- Antiemetics not usually required.

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
DOCEtaxel (weekly)	36 mg/m^2	IV in 100 to 250 mL NS over 1 hour (use non-DEHP equipment)

Repeat weekly for 6 weeks followed by 2 weeks rest (1 cycle = 8 weeks) x 4 cycles (32 weeks)
Discontinue if no response after 1 cycle (8 weeks).

DOSE MODIFICATIONS:

1. Hematological:

ANC (x 10^9/L)	Platelets (x 10^9/L)	Dose	Dose after Neutropenic Sepsis on DOCEtaxel
greater than or equal to 1.5	greater than or equal to 90	100%	75%
1.0 to less than 1.5	70 to less than 90	75%	75%
less than 1.0	less than 70	delay	delay

2. Hepatic Dysfunction:

Alkaline Phosphatase		ALT	Dose
less than 2.5 x ULN	And	less than or equal to 1.5 x ULN	100%
2.5 to 5 x ULN	And	1.6 to 5 x ULN	75%
greater than 5 x ULN	Or	greater than 5 x ULN	Discuss with contact physician

ULN = upper limit of normal

3. Severe Fatigue:

For patients who experience severe fatigue, consider:

- dose reduction to 75% (27 mg/m^2) and/or
- schedule adjustment to weekly DOCEtaxel for 3 weeks followed by 1 week rest (1 cycle = 4 weeks) to complete 32 weeks total treatment *including previous DOCEtaxel treatments* given on 8-week cycle schedule)

PRECAUTIONS:

1. **Fluid retention:** Although fluid retention is less likely to occur with weekly DOCEtaxel, dexamethasone premedication must be given to reduce incidence of severity of fluid retention.
2. **Infusion-related reactions:** Reactions are common but it is not necessary to routinely initiate the infusion slowly. If slow initiation of infusion is needed, start infusion at 30 mL/h x 5 minutes, then 60 mL/h x 5 minutes, then 120 mL/h x 5 minutes, then complete infusion at 250 mL/h (for 500 mL bag, continue 250 mL/h for 5 minutes and then complete infusion at 500 mL/h). Refer to BC Cancer Infusion-Related Reactions Guidelines.
3. **Extravasation:** DOCEtaxel causes pain and tissue necrosis if extravasated. Refer to BC Cancer Extravasation Guidelines.

4. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
5. **Hepatic dysfunction:** DOCEtaxel undergoes hepatic metabolism. Hepatic dysfunction (particularly elevated AST or ALT) may lead to increased toxicity and usually requires a dose reduction. Baseline liver enzymes are recommended before cycle 1 and then if clinically indicated (eg. Repeat liver enzymes prior to each treatment if liver enzymes are elevated, liver metastases are present or there is severe toxicity such as neutropenia). If liver enzymes are normal and there is no evidence of liver metastases or severe toxicity, check liver enzymes after 2 cycles (ie, at cycle 3). Note: this information is intended to provide guidance but physicians must use their clinical judgment when making decisions regarding monitoring and dose adjustments.
6. **Lacrimation:** DOCEtaxel is secreted into lacrimal fluid and excessive lacrimation leading to tear duct stenosis may occur, especially with weekly DOCEtaxel. Early intubation should be considered.[4]

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

References:

1. Hainsworth JD, Burris HA III, Yardley DA, Bradof JE, et al. Weekly docetaxel in the treatment of elderly patients with advanced breast cancer: a Minnie Pearl cancer research network phase II trial. J Clin Oncol 2001;19:3500-05.
2. Burstein HJ, Manola J, Younger J, Parker LM, et al. Docetaxel administered on a weekly basis for metastatic breast cancer. J Clin Oncol 2000;18:1212-9.
3. Stemmler J, Mair W , Stauch M et al. Weekly docetaxel with or without corticosteroid premedication as first or second-line treatment in patients (pts) with metastatic breast cancer (MBC). [Abstract 231] Proc Am Soc Clin Oncol 2002;21:58a.
4. Esmaeli B, Hortobagyi G, Esteva F et al. Canalicular stenosis secondary to weekly docetaxel: a potentially preventable side effect. Ann Oncol 2002;13:218-21.