

BCCA Protocol Summary for Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma Using Docetaxel

Protocol Code	GOOVDOC
Tumour Group	Gynecologic Oncology
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PREFACE:

- In platinum sensitive disease: patients will ideally receive doublet therapy consisting of carboplatin plus either a taxane or gemcitabine (e.g., GOOVCA^{TR}, GOOVCA^{DR}, GOOVCA^G)
- In platinum resistant disease (i.e., cancer progresses within six months of completing a platinum-containing treatment protocol): patients will ideally receive single agent carboplatin, as it is the least toxic and most convenient choice of the equally efficacious agents available (i.e., GOOVCA^{RB})
- In platinum refractory disease (i.e., cancer progresses while being treated with a platinum) choose between available agents based upon toxicity profile and convenience of dosing regimen. Options include: GOOV^{TOP}, GOOL^{DOX}, GOOV^{GEM}, GOOV^{ETO}, GOOV^{VIN}, GOOV^{TAX3}, GOOV^{DOC}. If gemcitabine (GOOV^{GEM}), topotecan (GOOV^{TOP}) or pegylated liposomal doxorubicin (GOOV^{LDOX}) is used, only one of these options will be reimbursed in any one patient. Subsequently, if a patient is thought likely to benefit from one of the other two, a request should be submitted to the BCCA Compassionate Access Program (CAP).
- Patients who will not benefit from further therapy after second or subsequent rounds of chemotherapy can be identified by the following formula: “day 1 of treatment N to day of progression on treatment N+1 is less than or equal to 6 months.” They should be offered symptomatic management or investigational protocols.

ELIGIBILITY:

- Platinum refractory ovarian, primary peritoneal or Fallopian tube carcinoma
- Platinum resistant ovarian, primary peritoneal or Fallopian tube carcinoma in cases where patient-specific concerns dissuade the clinician from selecting single-agent carboplatin
- Platinum sensitive ovarian, primary peritoneal or Fallopian tube carcinoma in cases where actual or potential toxicity precludes the use of carboplatin or cisplatin alone or in combination with a taxane or gemcitabine.
- If used at the time of second, or greater, relapse, more than six months benefit to the two preceding chemotherapy regimens must have occurred (i.e., day 1 of treatment N to day of progression on treatment N+1 must be greater than 6 months)¹
- Adequate hematologic, liver and cardiac function
- PS ECOG 3 or better
- A “Class II Drug Registration Form” must be submitted at the time of initiation of treatment (included in BCCA PPPO; separate submission not needed if PPPO used)

EXCLUSIONS:

- Relapse of platinum sensitive disease (i.e., greater than 6 months from end of first-line treatment). See PREFACE, above. Exception: cases of unacceptable toxicity from platinum agent

TESTS:

- Baseline: CBC & diff, LFT's
- Before each treatment: CBC & diff; LFT's if indicated (see Precaution note 5); tumour markers (at physician's discretion)
- At Cycle 4 check LFT's
- Imaging (at physician's discretion)

PREMEDICATIONS:

- Dexamethasone 8 mg PO bid for 3 days, starting one day prior to each docetaxel administration. Patient must receive minimum of 3 doses pre-treatment.
- Additional antiemetics not usually required (see [SCNAUSEA](#))
- Docetaxel-induced onycholysis and cutaneous toxicity of the hands may be prevented by wearing frozen gloves starting 15 minutes before docetaxel infusion until 15 minutes after end of docetaxel infusion; gloves should be changed after 45 minutes of wearing to ensure they remain cold during the entire docetaxel infusion.

TREATMENT:

Drug	Dose	BCCA Administration Guideline
Docetaxel	75 mg/m ²	IV in 250 mL* NS or D5W over 1 hour (see precaution #2) (use non-PVC equipment)

*If dose 75-185 mg, use 250 mL bag. If dose greater than 185 mg, use 500 mL bag.

Repeat every 21 days until progression or unacceptable toxicity occurs, to a maximum of 6 cycles. To continue beyond six cycles, submit a BCCA Compassionate Access Program (CAP) application.

DOSE MODIFICATIONS:

1. Hematological:

ANC (x 10 ⁹ /L)	Platelets(x 10 ⁹ /L)	Dose
greater than or equal to 1	greater than or equal to 100	100%
less than 1	less than 100	delay until recovery; subsequent doses at 60 mg/m ²

2. **Febrile Neutropenia:** Reduce dose to 60 mg/m² after first occurrence of febrile neutropenia. In the case of a second occurrence, use filgrastim (G-CSF) together with the same dose of docetaxel, or discontinue docetaxel.

3. Hepatic dysfunction:

Alkaline Phosphatase		AST +/-or ALT	Dose
less than 2.5 x ULN	and	less than or equal to 1.5 x ULN	75 mg/m ²
2.5 – 5 x ULN	and	1.6 – 5 x ULN	60 mg/m ²
greater than 5 x ULN	or	greater than 5 ULN	discuss with contact physician

ULN = upper limit of normal

PRECAUTIONS:

1. **Fluid retention:** Dexamethasone premedication must be given to reduce incidence and severity of fluid retention.
2. **Hypersensitivity** reactions to docetaxel 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 BCCA Hypersensitivity Guidelines.
3. **Extravasation:** Docetaxel causes pain and tissue necrosis if extravasated. Refer to BCCA 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) may lead to increased toxicity and usually requires a dose reduction. Check liver enzymes before cycle 1 and then if clinically indicated (e.g., 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 3 cycles (ie, at cycle 4). Note: this information is intended to provide guidance but physicians must use their clinical judgement when making decisions regarding monitoring and dose adjustments.

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

Date activated: 01 August 2003

Dated revised: 01 Sept 2010 (Frozen gloves option added for docetaxel-induced nail and skin toxicity)

References

1. Vasey PA. Role of docetaxel in the treatment of newly diagnosed advanced ovarian cancer. J Clin Oncol 2003;21(90100):136s-44s.