

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

**Protocol Code**

GOOVTOP

**Tumour Group**

Gynecologic Oncology

**Contact Physician**

Dr. Paul Hoskins

## PREFACE:

- In platinum sensitive disease: patients will ideally receive doublet therapy consisting of carboplatin plus either a taxane or gemcitabine (e.g., GOOVCTR, GOOVADR, GOOVAG)
- 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., GOOVARB)
- 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: GOOVTOP, GOOLDOX, GOOVGEM, GOOVETO, GOOVVIN, GOOVTAX3, GOOVDOC. If gemcitabine (GOOVGEM), topotecan (GOOVTOP) or pegylated liposomal doxorubicin (GOOVLDOX) 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 less than 6 months)<sup>1</sup>
- 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:

- creatinine clearance less than 40 mL/min. See DOSE MODIFICATIONS for reduced starting dose in patients with renal dysfunction

**TESTS:**

- Baseline: CBC & diff (including platelets), creatinine, tumor marker (at physician's discretion), imaging for tumour assessment (at physician's discretion)
- Before each treatment: CBC & diff (including platelets), tumor markers (at physician's discretion)
- Days 8 and 15 first cycle only (except if dose modification made): CBC & diff (including platelets) to determine nadir levels
- In future cycles, if clinically indicated: creatinine

**PREMEDICATIONS:**

- Antiemetic protocol for chemotherapy with low to low-moderate emetogenicity (see [SCNAUSEA](#))

**TREATMENT:**

Drug	Starting Dose	BCCA Administration Guideline
Topotecan	1.25 mg/m <sup>2</sup> /day x 5 days (days 1-5)*	IV in 50 mL NS over 30 minutes

Repeat 5-day treatment 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.

\* In heavily pre-treated patients, suggested starting dose is 1 mg/m<sup>2</sup>/day x 5 days

**DOSE MODIFICATIONS:****1. Hematological:**

(a) on treatment day:

ANC (x 10 <sup>9</sup> /L)		Platelets (x 10 <sup>9</sup> /L)	Dose
greater than or equal to 1.0	and	greater than or equal to 100	treat as per nadir
less than 1.0	and/or	less than 100	delay until recovery

(b) at nadir:

ANC (x 10 <sup>9</sup> /L)		Platelets (x 10 <sup>9</sup> /L)	Dose
less than or equal to 0.5	and/or	less than or equal to 75	↓ by 0.25 mg/m <sup>2</sup> /day

(c) Febrile neutropenia: decrease dose by 0.25 mg/m<sup>2</sup>/day. In the case of a second occurrence, use filgrastim (G-CSF) and maintain the same dose level, or discontinue topotecan treatment.

**2. Any Grade 3 or 4 toxicity (except nausea): decrease dose by 0.25 mg/m<sup>2</sup>/day**

### 3. Renal Dysfunction:

<b>Creatinine Clearance (mL/min)</b>	<b>Topotecan Dose</b>
greater than or equal to 40	100%
20-39	50%
less than or equal to 20	not recommended

$$\text{CrCl in mL/min} = \frac{1.04 \times (\text{weight in kg})(140 - \text{age in years})}{\text{SCr in micromol/L}}$$

### PRECAUTIONS:

1. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.

**Call Dr. Paul Hoskins 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 May 1999

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