

# BCCA Protocol Summary for Palliative Chemotherapy for Upper Gastrointestinal Tract Cancer (Gastric, Esophageal, Gall Bladder, Pancreas Carcinoma and Cholangiocarcinoma) and Metastatic Anal using Infusional Fluorouracil and Cisplatin

**Protocol Code**  
**Tumour Group**  
**Contact Physician**

**GIFUC**  
**Gastrointestinal**  
**GI Systemic Therapy**

## ELIGIBILITY:

- Metastatic or unresectable adenocarcinoma of the upper gastrointestinal tract (stomach, esophagus, gall bladder, pancreas, bile ducts)
- Metastatic squamous cell or cloacogenic carcinoma of the anal canal
- ECOG 0-2

## EXCLUSIONS:

- CNS metastases
- Uncontrolled high blood pressure, unstable angina, symptomatic congestive heart failure, myocardial infarction within the preceding 6 months, serious uncontrolled cardiac dysrhythmia
- Inadequate hepatic function (total bilirubin greater than 35 micromol/L, AST greater than 3x normal)
- Inadequate renal function (creatinine clearance less than 45 ml/min as calculated by Cockcroft/Gault formula – see page 3)

## TESTS:

- Baseline: CBC, diff and platelets, creatinine
- Prior to each treatment: CBC, diff and platelets, creatinine
- If clinically indicated: bilirubin, appropriate imaging studies

## PREMEDICATIONS:

This regimen is high moderate in emetogenic potential. See SCNAUSEA protocol.

## TREATMENT:

A cycle equals -

Drug	Dose	BCCA Administration Guideline
Cisplatin	25 mg/m <sup>2</sup>	IV in 100 mL NS over 30 min
Fluorouracil (5FU)	1000 mg/m <sup>2</sup> /day for 2 days (total dose = 2000 mg/m <sup>2</sup> over 48 h) Maximum dose = 5000 mg/48 h	IV in D5W to a total volume of 96 mL by continuous infusion at 2 mL/h via appropriate infusor device*

\*For total dose greater than 4600 mg, to a total volume of 240 mL by continuous infusion at 5 mL/h.

*(Inpatients: 1000 mg/m<sup>2</sup>/day in 1000 mL D5W by continuous infusion daily over 24 h for 2 days)*

Patients with PICC lines should have a weekly assessment of the PICC site for evidence of infection or thrombosis.

Repeat every 7 days for 12 weeks. One cycle = 1 week. (maximum = 24 cycles). Most responding patients will manifest benefit by 6-8 cycles.

## DOSE MODIFICATIONS:

### 1. Hematological:

ANC (x10 <sup>9</sup> /L)		Platelets (x10 <sup>9</sup> /L)	Dose (both drugs)
greater than or equal to 1.0	and	greater than or equal to 100	100%
less than 1.0	or	less than 100	delay

### 2. Renal dysfunction:

Delay for one week if serum creatinine greater than 3 x ULN. If serum Creatinine less than 3 x ULN adjust cisplatin dose as follows:

Creatinine Clearance (by Cockcroft/Gault formula)	Dose - Cisplatin only
greater than or equal to 60 ml/min	100%
45 – 59 ml/min	50%
less than 45 ml/min	delay

Cockcroft/Gault formula:

$$CrCl = \frac{N (140 - \text{age}) \times \text{weight (kg)}}{\text{serum creatinine (micromol/L)}}$$

Where N = 1.04 for females, and 1.23 for males

### 3. Gastrointestinal toxicity:

Grade	Stomatitis	Diarrhea	Dose Fluorouracil
Grade 1	Painless ulcers, erythema or mild soreness	Increase of 2-3 stools/day or nocturnal stools; or moderate increase in loose watery colostomy output	100%
Grade 2	Painful erythema, edema, or ulcers but can eat	Increase of 4-6 stools/day, or nocturnal stools or moderate increase in loose watery colostomy output	75%
Grade 3 or 4	As above, but cannot eat, mucosal necrosis, requires parenteral support.	Increase of greater than 7 stools/day or grossly bloody diarrhea, or incontinence, malabsorption; or severe increase in loose watery colostomy output requiring parenteral support	Discontinue or delay until toxicity resolved then resume at 50%.

### 4. Hand-Foot Syndrome

Grade	Hand-Foot Syndrome	Dose Fluorouracil
Grade 1	Skin changes or dermatitis without pain e.g. erythema, peeling	100%
Grade 2	Skin changes with pain not interfering with function	75% until resolved then consider increasing dose by 10%
Grade 3	Skin changes with pain, interfering with function	Delay until resolved then resume at 75%

### 5. Hepatic dysfunction: Omit treatment if bilirubin greater than 85 micromol/L unless secondary to biliary obstruction. Refer to BCCA Cancer Drug Manual.

**PRECAUTIONS:**

1. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
2. **Renal Toxicity:** Nephrotoxicity is common with cisplatin. Encourage oral hydration. Avoid nephrotoxic drugs such as aminoglycoside antibiotics.
3. **Myocardial** ischemia and angina occurs rarely in patients receiving Fluorouracil. Development of cardiac symptoms including signs suggestive of ischemia or of cardiac arrhythmia is an indication to discontinue treatment.

**Call the GI Systemic Therapy physician at your regional cancer centre or Dr. Sanjay Rao 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 May 2011 (minor edit in Test Section)