

BCCA Protocol Summary for Palliative Chemotherapy for Pancreatic Adenocarcinoma, Gallbladder Cancer, and Cholangiocarcinoma Using Gemcitabine

Protocol Code *GIPGEM*
Tumour Group *Gastrointestinal*
Contact Physician *GI Systemic Therapy*

ELIGIBILITY:

- Metastatic or unresectable pancreatic adenocarcinoma, gallbladder cancer or cholangiocarcinoma
- ECOG 0-2
- [Class II form must be completed](#)

TESTS:

- Baseline: CBC, diff and platelets; creatinine, bilirubin, appropriate tumour markers and imaging study
- Prior to each treatment: CBC, diff and platelets
- If clinically indicated: bilirubin, creatinine
- After cycle 1, then every 2 cycles: appropriate tumour markers and imaging studies

PREMEDICATIONS:

- Antiemetic protocol for non-emetogenic chemotherapy (see SCNAUSEA).

TREATMENT:

Cycle	Drug	Dose	BCCA Administration Guideline
1	Gemcitabine	1000 mg/m ² /week x 7 weeks then 1 week rest (=8 week cycle)	IV in 250 mL NS over 30 minutes
<i>During Cycle 1: If 2 consecutive doses are omitted then abandon cycle and after toxicity resolved begin Cycle 2 at 75% previous dose.</i>			
2 etc.	Gemcitabine	1000 mg/m ² /week x 3 weeks then 1 week rest (=4 week cycle)	IV in 250 mL NS over 30 minutes

Cycle	1								2				3				
Week	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	<i>etc</i>
Chemo	x	x	x	x	x	x	x		x	x	x		x	x	x		

Continue treatment as long as there is evidence of a clinical response, usually a partial response or stable disease associated with symptom improvement (decreased pain, weight gain, improved performance status) or until there is unacceptable toxicity

DOSE MODIFICATIONS:

1. Hematology – On Treatment Day

ANC (x 10⁹/L)	Platelets (x 10⁹/L)	Dose
greater than 1	and greater than 100	100%
0.5-1	or 50-100	75% or delay, based on clinical assessment
less than 0.5	or less than 50	delay

2. Non – Hematologic Toxicities

Grade	Stomatitis	Diarrhea	Dose
1	Painless ulcers, erythema or mild soreness	Increase of 2-3 stools/day or mild increase in loose watery colostomy output	100%
2	Painful erythema, edema, or ulcers but can eat	Increase of 4-6 stools, or nocturnal stools or mild increase in loose watery colostomy output	Omit until toxicity resolved then resume at 100%
3	Painful erythema, edema, or ulcers and cannot eat	Increase of 7-9 stools/day or incontinence, malabsorption; or severe increase in loose watery colostomy output	Omit until toxicity resolved then resume at 75%
4	Mucosal necrosis, requires parenteral support	Increase of 10 or more stools/day or grossly bloody diarrhea, or grossly bloody colostomy output or loose watery colostomy output requiring parenteral support; dehydration	Omit until toxicity resolved then resume at 50%.

- Doses reduced for toxicity should not be re-escalated.
- If doses must be omitted for Grade 2 toxicity twice in previous cycles, then commence next cycle at 75% dose when treatment is resumed.

PRECAUTIONS:

1. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
2. **Renal Dysfunction:** Irreversible renal failure associated with hemolytic uremic syndrome may occur (rare). Use caution with pre-existing renal dysfunction.
3. **Pulmonary Toxicity:** Acute shortness of breath may occur. Discontinue treatment if drug-induced pneumonitis is suspected.

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: 01 January 1999

Date Revised: 1 Dec 2011 (Eligibility revised)

References:

1. Burris HA 3rd, Moore MJ, Andersen J et al. Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: a randomized trial. *J Clin Oncol.* 1997 Jun;15(6):2403-13.
2. Dingle BH, Rumble RB, Brouwers MC et al. The role of gemcitabine in the treatment of cholangiocarcinoma and gallbladder cancer: a systematic review. *Can J Gastroenterol.* 2005 Dec;19(12):711-6