

# BCCA Protocol Summary for Maintenance Therapy of Advanced Non-Small Cell Lung Cancer (NSCLC) With Pemetrexed

**Protocol Code:** *ULUAVPMTN*

**Tumour Group:** *Lung*

**Contact Physician:** *Dr. Barb Melosky*

## ELIGIBILITY:

- Advanced non-small cell lung cancer
  - Restricted to disease of *non-squamous cell* histology
- No disease progression after 4 cycles of first-line platinum-based doublet not containing pemetrexed
- Maintenance pemetrexed is to be started 21 to 42 days after the fourth cycle of the first-line platinum-based doublet
- ECOG performance status 0-1 at start of maintenance
- BC Cancer Agency Compassionate Access Program (CAP) approval must be obtained.

## EXCLUSIONS:

- ECOG 2-4
- Prior treatment with first-line platinum analog and pemetrexed (ULUAVPP)

## TESTS:

- Baseline: CBC & differential, platelets, creatinine, liver function tests, bilirubin
- Before each treatment: CBC & differential, platelets, liver function tests, bilirubin
- Weekly: CBC & differential, platelets during cycles 1 and 2; may be omitted in subsequent cycles
- If clinically indicated: creatinine

## PREMEDICATIONS:

- **Vitamin supplementation mandatory** starting at least 7 days prior to the first cycle, and to continue while on treatment until 21 days after last Pemetrexed dose:
  - Folic Acid 0.4 mg PO daily
  - Vitamin B12 1000 mcg IM every 9 weeks
- Prophylaxis for skin rash: dexamethasone 4 mg PO BID for 3 days, beginning the day before chemotherapy. (May proceed with chemotherapy even if patient has not taken the pre-treatment dexamethasone doses. Instruct patient to begin immediately.)

**TREATMENT:**

Drug	Dose	BCCA Administration Guideline
Pemetrexed	500 mg/m <sup>2</sup>	IV in 100 mL NS over 10 minutes

- Repeat every 21 days x 6 cycles. If there is continued evidence of response or stable disease by imaging or tumour markers, apply for up to 6 additional cycles of via Compassionate Access Program.

**DOSE MODIFICATIONS:****1. HEMATOLOGY****Based on day 1 counts**

ANC (x 10 <sup>9</sup> /L)		Platelets (x 10 <sup>9</sup> /L)	Dose
greater than or equal to 1.5	and	greater than or equal to 100	100%
less than 1.5	or	less than 100	Delay

**Based on nadir counts**

ANC (x 10 <sup>9</sup> /L)		Platelets (x 10 <sup>9</sup> /L)	Dose
greater than or equal to 0.5	and	greater than or equal to 50	100%
less than 0.5	and	greater than or equal to 50	75%
any	and	less than 50	50%

**2. RENAL DYSFUNCTION**

Creatinine Clearance mL/min	Dose
greater than or equal to 45	100%
less than 45	Delay

### 3. MUCOSITIS

For next cycle

Mucositis Grade	Dose
0-2	100%
3-4	50% previous dose*
<b>*Discontinue treatment after two dose reductions</b>	

### 4. OTHER TOXICITIES

For any other grade 3 or higher toxicity, delay treatment until toxicity resolves, then resume with 25% dose decrease if considered appropriate to resume by attending oncologist

#### PRECAUTIONS:

- Vitamin supplements:** Appropriate prescription of folic Acid and vitamin B12 is essential. The incidence of adverse events such as febrile neutropenia related to pemetrexed is higher without vitamin supplementation.
- NSAIDS:** Concurrent nonsteroidal anti-inflammatory agents should be avoided as they may decrease the renal clearance of pemetrexed.
- Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.

**Contact Dr. Barb Melosky or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.**

Date activated: 1 Feb 2011

Date revised:

#### REFERENCES:

Ciuleanu T, Brodowicz T, Zielinski C, et al. Maintenance pemetrexed plus best supportive care versus placebo plus best supportive care for non-small-cell lung cancer: a randomised, double-blind, phase 3 study. *Lancet* 2009;374:1432-40.