BCCA Protocol Summary for Therapy of Acute Myeloid Leukemia Using Low Dose Cytarabine

Protocol Code	*LKAMLCYT*
Tumour Group	*Leukemia/BMT*
Contact Physician	*Dr. Stephen Nantel*

ELIGIBILITY:

- AML patients not considered candidates for standard treatment
- Not a candidate for remission induction with "7+3" due to co-morbidity/age
- Patient preference for "more aggressive" therapy as compared to oral hydroxyurea and transfusion support
- Good or intermediate risk cytogenetics by MRC criteria
- Able to administer SC cytarabine at home and pick-up medication from BCCA/CON pharmacy

EXCLUSIONS:

- High risk cytogenetics by MRC criteria
- AML NOT requiring transfusion support greater than once per month and with ANC greater than 1.0
- ECOG performance status greater than 2
- Unable to self-administer SC cytarabine

TESTS:

- Baseline: bone marrow examination and formal cytogenetics, CBC and differential, bilirubin, serum creatinine, BUN
- Before each treatment: CBC and differential
- If clinically indicated: bilirubin, GGT, Alk Phos, LDH, ALT, Creatinine, Uric Acid

PREMEDICATIONS:

As required.

TREATMENT:

Drug	Dose	BCCA Administration Guideline
cytarabine (cytosine arabinoside)	20 mg BID for 10 days every 4 to 6 weeks	SC

****Prescriptions need to be provided for pharmacy <u>at least 24hr</u> before patient pick-up****

Patients may self-administer at home after initial training, following "Safe Handling" process.

- Treatment for a maximum of 4 cycles of therapy (CAP required for further treatment)
- Treatment will stop before 4 cycles if:
  - CR is achieved after fewer cycles
  - Prohibitive toxicity develops defined as:
    - Low ANC with Sepsis requiring IV antibiotics and/or hospital admission
    - Low platelet count with platelet refractoriness and/or bleeding

If patient achieves CR by conventional criteria with duration greater than 12 months they <u>MAY</u> be eligible for retreatment on relapse. (CAP required for further treatment)

DOSE MODIFICATIONS:

1. **Hematological:** The aim of this therapy is suppression of the bone marrow. An attempt should be made to maintain a white cell count of 2-5 x 10^9/L.
   a) Cycle 1 only: Patients receiving their FIRST cycle of this therapy are very likely to have severe neutropenia and thrombocytopenia as they have Acute Leukemia. Treating physician to determine parameters for treatment. Supportive care with platelet and PRBC transfusions are recommended as per standard recommendations for management of patients with marrow failure.
   b) Cycle 2-4: Prior to cycle 2-4 of cytarabine, the white cell count should be greater than 2, the neutrophil count greater than 1.5 x 10^9/L, and the platelet count greater than 100 x 10^9/L. Absolute dose reduction guidelines cannot be given as they will vary from patient to patient. Consultation with a member of the Leukemia/BMT group is suggested if counts are of concern.
2. **Renal:** No adjustment required for standard doses.
3. **Hepatic:** dose reduction may not be necessary[3,2]; if adjusted the following guideline has been used[3]: a 50% initial dose reduction if bilirubin greater than or equal to 34 micromol/L and increase as tolerated

PRECAUTIONS:

1. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
2. Cytarabine syndrome has not been reported with this low dose cytarabine.
3. **Oral Ulceration:** Cytarabine may cause oral ulcers; if these persist after one or two cycles, the dose should be reduced by 25-50% and the patient reassessed.

Call any member of the Leukemia/BMT Program of BC at (604) 875-4863 or (604-875-5000 24 hours via Vancouver General Hospital paging) with any problems or questions regarding this treatment program.

Date activated: 01 Jan 2012

Date last revised: 1 Jul 2015 (Eligibility clarified)

References:

1. Burnett, AK et al. Cancer 109: 1114-1124, 2007
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3. McEvoy GK. AHFS 2006 Drug Information. Bethesda, Maryland: American Society of Health-System Pharmacists, Inc.; 2006. p. 1003-1007.
4. Rose BD editor. Cytarabine. www.uptodate.com ed. Waltham, Massachusetts: UpToDate 14.3; 2006.
5. DRUGDEX® Evaluations (database on the Internet). Cytarabine. Thomson MICROMEDEX®, 2006. Available at: www.micromedex.com. Accessed 21 December 2006
6. Chng WJ. Cytarabine syndrome revisited. Br J of Haematol 2003;122(6):875.
7. Ek T, Abrahamsson J, Ek T, et al. The paediatric cytarabine syndrome can be viewed as a drug-induced cytokine release syndrome.[comment]. Br J Haematol 2004;124(5):691.