NCCP Chemotherapy Regimen

High Dose Cytarabine Therapy

INDICATIONS FOR USE:

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>ICD10</th>
<th>Regimen Code</th>
<th>Reimbursement Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consolidation chemotherapy for the treatment of patients with Acute Myeloid Leukaemia (AML)</td>
<td>C92</td>
<td>00365a</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patient's individual clinical circumstances.

Treatment is administered on Day 1, 3 and 5.

Treatment with cycle 2 may proceed on count recovery.

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Diluent and rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3,5</td>
<td>Cytarabine</td>
<td>3000mg/m^2 AM</td>
<td>IV infusion</td>
<td>500mls NaCl 0.9% over 4 hours</td>
</tr>
<tr>
<td>1,3,5</td>
<td>Cytarabine</td>
<td>3000mg/m^2 PM (12 hours after start of AM infusion)</td>
<td>IV infusion</td>
<td>500mls NaCl 0.9% over 4 hours</td>
</tr>
</tbody>
</table>

ELIGIBILITY:
- Patients < 60 years generally. May be used in older patients if deemed fit for intensive therapy by prescribing consultant.
- ECOG status 0-2

EXCLUSIONS:
- Hypersensitivity to cytarabine or any of the excipients
- Breast feeding
- Pregnancy

PRESCRIPTIVE AUTHORITY:
The treatment plan must be initiated by a Consultant Haematologist working in the area of haematological malignancies.
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TESTS:
Baseline tests:
- FBC, renal and liver profile, Glucose
- Coagulation screen (Activated Partial Thromboplastin time (APTT), Prothrombin time (PT), fibrinogen level)

Regular tests:
- FBC, renal and liver profile, glucose daily or as clinically indicated
- Coagulation profile: APTT, PT, fibrinogen level at least twice weekly or more frequently as clinically indicated

Disease monitoring:
Disease monitoring should be in line with the patient’s treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:
- Any dose modification should be discussed with a Consultant
- Dose reductions not generally undertaken in induction regimens
- Note: Dose modification required in renal impairment (Ref Table 1)

Renal and Hepatic Impairment:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Renal Impairment</th>
<th>Hepatic Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytarabine</td>
<td>CrCl (ml/min)</td>
<td>Dose</td>
</tr>
<tr>
<td>&gt;60</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>46-60</td>
<td>60%</td>
<td></td>
</tr>
<tr>
<td>31-45</td>
<td>50%</td>
<td></td>
</tr>
<tr>
<td>&lt;30</td>
<td>CI</td>
<td></td>
</tr>
</tbody>
</table>

SUPPORTIVE CARE:
EMETOGENIC POTENTIAL: Moderate (Refer to local policy).

PREMEDICATIONS:
To prevent a chemical induced conjunctivitis developing with cytarabine, Prednisolone eye drops (e.g. Pred Mild) 1-2 drops per eye 4 hourly during waking hours prior to cytarabine and continued 5 days post treatment should be considered.

OTHER SUPPORTIVE CARE:
- Proton pump Inhibitor (Refer to local policy)
- Anti-viral prophylaxis (Refer to local policy)
- Anti-fungal prophylaxis (Refer to local policy)
ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS:
The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- **Myelosuppression**: Cytarabine is a potent bone marrow suppressant. Patients receiving this drug must be under close medical supervision and, during induction therapy, should have leucocyte and platelet counts performed daily. Bone marrow examinations should be performed frequently after blasts have disappeared from the peripheral blood.

- **Neurotoxicity**: This may occur in patients treated with high dose cytarabine. Assess cerebellar function prior to each cytarabine dose. The risk of neurotoxicity is enhanced in the presence of renal impairment. Ensure that dose of cytarabine is adjusted in renal impairment (Ref Table 1).

- **Cytarabine syndrome**: Treatment with cytarabine may cause a 'Cytarabine Syndrome' characterised by flu-like symptoms, skin rash and occasionally chest pain.

DRUG INTERACTIONS:
- Current drug interaction databases should be consulted for more information.

ATC CODE:
Cytarabine - L01BC01

REFERENCES:
3. AML 17 Version 8.0 (October 2012) accessed at www.aml17.cardiff.ac.uk/files/files/htm