**NCCP Chemotherapy Regimen**

**Cyclophosphamide 2000mg/m² For Stem Cell Mobilisation**

**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>Mobilisation of peripheral blood stem cells for future stem cell rescue following high dose chemotherapy</td>
<td></td>
<td>00438a</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

*If a reimbursement indicator (e.g. ODMS, CDS) is not defined, the drug and its detailed indication have not been assessed through the formal HSE reimbursement process.*

**TREATMENT:**

A single cycle is administered prior to stem cell harvest
The recommended cut off level for stem cell harvest is Hb ≥ 8.0g/dL and Platelets >20 x 10⁹/L

**Note:** Hydration therapy is required for the safe administration of cyclophosphamide (See Table below)

<table>
<thead>
<tr>
<th>Day (Time)</th>
<th>Drug</th>
<th>Dose</th>
<th>Route and Method of Administration</th>
<th>Diluent &amp; Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (T 0)</td>
<td>bMesna</td>
<td>800mg/m²</td>
<td>IV bolus</td>
<td>Into the side arm of a fast-flowing 0.9% NaCl drip immediately prior to cyclophosphamide</td>
</tr>
<tr>
<td>1 (T 0)</td>
<td>aCyclophosphamide</td>
<td>2000mg/m²</td>
<td>IV infusion</td>
<td>1000ml 0.9% NaCl over 2hours</td>
</tr>
<tr>
<td>1 (T +3 hours)</td>
<td>Mesna</td>
<td>800mg/m²</td>
<td>bIV Bolus</td>
<td>Into the side arm of a fast-flowing 0.9% NaCl drip 4 hours post start of cyclophosphamide</td>
</tr>
<tr>
<td>1 (T +6 hours)</td>
<td>Mesna</td>
<td>800mg/m²</td>
<td>bIV Bolus</td>
<td>Into the side arm of a fast-flowing 0.9% NaCl drip 8 hours post start of cyclophosphamide</td>
</tr>
<tr>
<td>4c</td>
<td>G-CSF</td>
<td>10mcg/kg (round to nearest full syringe)</td>
<td>SC</td>
<td>Continue daily until stem cell harvesting has been completed.</td>
</tr>
</tbody>
</table>

*Cyclophosphamide Hydration: (Refer to local policy or see suggested hydration below). Pre-Hydration: Administer 1000 mL sodium chloride 0.9% over 2-3 hours. Post-Hydration: Administer 1000 mL sodium chloride 0.9% over 2-3 hours. *

*Alternative Mesna regimens may be used at the discretion of the prescribing consultant*

*Alternative G-CSF starting day may be used at the discretion of the prescribing consultant*

Maintain strict fluid balance during therapy, by (1) monitoring fluid balance and (2) daily weights. If fluid balance becomes positive by >1000mls or weight increases by >1 Kg, the patient should be reviewed and consideration given to diuresing with furosemide

Consider plerixifor in poorly mobilized patients at the discretion of prescribing consultant

**ELIGIBILITY:**

- Indications as above

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EXCLUSIONS:
- Hypersensitivity to cyclophosphamide or any of the excipients.

PRESCRIPTIVE AUTHORITY:
The treatment plan must be initiated by a Consultant Haematologist working in the area of haematological malignancies.

TESTS:
Baseline tests:
- FBC, renal and liver profile
- Uric acid, LDH
- Creatinine Clearance
- ECG +/- echocardiogram if clinically indicated
- Virology screen - Hepatitis B (HBsAg, HBcoreAb), Hepatitis C, HIV.

*See Adverse Effects/Regimen Specific Complications re Hepatitis B Reactivation

Regular tests:
- FBC, renal and liver profile required daily

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.
- This is a single dose therapy used as priming for stem cell collection, therefore once decision has been made to proceed there is generally no dose reduction

Renal and Hepatic Impairment:
Table 1: Recommended dose modifications in patients with renal or hepatic impairment

<table>
<thead>
<tr>
<th>Drug</th>
<th>Renal Impairment</th>
<th>Hepatic Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclophosphamide</td>
<td>Cr Cl (ml/min)</td>
<td>Dose</td>
</tr>
<tr>
<td></td>
<td>&gt;20</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>10-20</td>
<td>75%</td>
</tr>
<tr>
<td></td>
<td>&lt;10</td>
<td>50%</td>
</tr>
</tbody>
</table>

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: High (Refer to local policy).

PREMEDICATIONS:
Hydration regimen for high dose cyclophosphamide (See suggested hydration above or refer to local policy)
OTHER SUPPORTIVE CARE:

- Proton pump inhibitor (Refer to local policy)
- PJP prophylaxis. Do not give co-trimoxazole for 2 weeks prior to collection. Recomence when collection completed (Refer to local policy)
- Tumour lysis syndrome prophylaxis (Refer to local policy)
- Anti-viral prophylaxis (Refer to local policy)
- Anti-fungal prophylaxis (Refer to local policy)
- All patients must receive irradiated cellular blood components starting 7 days prior to conditioning and until 12 months after stem cell infusion to prevent transfusion associated graft versus host disease.

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated appropriately.
- **Haemorrhagic cystitis:** This may occur with this regimen. Ensure patient is well hydrated.
- **Hepatitis B Reactivation:** All patients should be tested for both HBsAg and HBCoreAb as per local policy. If either test is positive, such patients should be treated with lamivudine 100 mg/day orally, for the entire duration of chemotherapy and for six months afterwards. Such patients should also be monitored with frequent liver function tests and hepatitis B virus DNA at least every two months. If the hepatitis B virus DNA level rises during this monitoring, management should be reviewed with an appropriate specialist with experience managing hepatitis and consideration given to stopping chemotherapy.

DRUG INTERACTIONS:

- Current drug interaction databases should be consulted for more information e.g interaction potential with CYP3A4 inhibitors/ inducers.

ATC CODE:

Cyclophosphamide - L01AA01

REFERENCES:


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<table>
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<tr>
<th>Version</th>
<th>Date</th>
<th>Amendment</th>
<th>Approved By</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>23/11/2018</td>
<td></td>
<td>Dr Kamal Fadalla</td>
</tr>
</tbody>
</table>

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

1 ODMS – Oncology Drug Management System
CDS – Community Drug Schemes (CDS) including the High Tech arrangements of the PCRS community drug schemes
Further details on the Cancer Drug Management Programme is available at; http://www.hse.ie/eng/services/list/5/cancer/proinfo/medonc/cdmp/