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>

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 2 hours</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 3 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 6 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.
- bAlternative Mesna regimens may be used at the discretion of the prescribing consultant
- cAlternative 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 >1Kg, the patient should be reviewed and consideration given to diuresing with furosemide

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

ELIGIBILITY:
- Indications as above

NCCP Regimen: Cyclophosphamide 2g/m² Stem Cell Mobilisation
Published: 23/11/2018
Review: 01/03/2026
Version number: 2

Tumour Group: Lymphoma and Myeloma
NCCP Regimen Code: 00438
IHS Contributors: Dr Kamal Fadalla
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The information contained in this document is a statement of consensus of NCCP and ISMO or IHS professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is the responsibility of the prescribing clinician. and is subject to HSE’s terms of use available at http://www.hse.ie/eng/Disclaimer

This information is valid only on the day of printing, for any updates please check www.hse.ie/NCCPchemoregimens
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>
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<tr>
<th>Drug</th>
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<th>Hepatic impairment</th>
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<tr>
<td>Cyclophosphamide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cr Cl (ml/min)</td>
<td>Dose</td>
<td>Severe impairment: Clinical Decision</td>
</tr>
<tr>
<td>&gt;20</td>
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<tr>
<td>10-20</td>
<td>75%</td>
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PRESCRIPTIVE AUTHORITY:

TESTS:

Baseline tests:

Regular tests:

Disease monitoring:

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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 infuision 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: Patients should be tested for both HBsAg and HBcoreAb as per local policy. If either test is positive, such patients should be treated with anti-viral therapy. (Refer to local infectious disease policy). These patients should be considered for assessment by hepatology.

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

REFERENCES:

<table>
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<tr>
<th>Version</th>
<th>Date</th>
<th>Amendment</th>
<th>Approved By</th>
</tr>
</thead>
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<tr>
<td>1</td>
<td>23/11/2018</td>
<td></td>
<td>Dr Kamal Fadalla</td>
</tr>
<tr>
<td>2</td>
<td>01/03/2021</td>
<td>Updated recommendation for hepatic impairment and adverse effects (hepatitis B reactivation)</td>
<td>Dr Kamal Fadalla</td>
</tr>
</tbody>
</table>

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.