Plerixafor and G-CSF 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>Is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in adult patients with lymphoma and multiple myeloma whose cells mobilise poorly</td>
<td>C85 C90</td>
<td>00536a</td>
<td>Hospital</td>
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</table>

*If the reimbursement status is not defined, the indication has yet to be assessed through the formal HSE reimbursement process.

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.

Plerixafor is administered by subcutaneous injection 11 hours (+/- 1 hour) prior to initiation of each apheresis following 4 day pre-treatment with G-CSF.

A total of up to 3 doses of plerixafor is recommended.

**Day** | **Drug** | **Dose** | **Route** | **Cycle** |
---|---|---|---|---|
1 onwards | G-CSF | 10mcg/kg (round to nearest whole syringe) | sc | Given in the morning from Day 1 onwards until harvest complete |
4 onwards | Plerixafor | 20mg | sc | Given in evening with initiation of apheresis on morning of day 5 (11 hours +/- 1 hour later). Continue to administer each night if required, until harvest complete. This should be to a maximum of 3 doses, |

*A flat dose of 20mg is recommended for patients weighing 65-83kg. A dose of 0.24mg/kg is recommended for patients weighing <65kg or > 83kg. The dose should not exceed 40mg/day. The weight used to calculate the dose of plerixafor should be obtained within 1 week before the first dose of plerixafor. Plerixafor dose and treatment of patients weighing more than 175% of ideal body weight have not been investigated. Ideal body weight can be determined using the following equations:

- Male (kg): 50 + 2.3 x ((Height (cm) x 0.394) – 60)
- Female (kg): 45.5 + 2.3 x ((Height (cm) x 0.394) – 60)

ELIGIBILITY:
- Indication as above

EXCLUSIONS:
- Hypersensitivity to plerixafor 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

Regular tests:
- FBC, renal and CD34 count 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.

Renal and Hepatic Impairment:

<table>
<thead>
<tr>
<th>Renal Impairment</th>
<th>Hepatic Impairment</th>
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<tbody>
<tr>
<td>Cr Cl (ml/min)</td>
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<tr>
<td>20-50</td>
<td>Reduce dose by 1/3 to 0.16mg/kg</td>
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<td>&lt; 20 or haemodialysis</td>
<td>insufficient clinical experience to make dose recommendations</td>
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<td>Based on increasing exposure with increasing body weight the dose should not exceed 27 mg/day if the creatinine clearance is lower than 50 ml/min</td>
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Supportive Care:

Emetogenic Potential: Minimal (Refer to local policy).

Premedications: None

Other Supportive Care: No specific recommendations

Adverse Effects / Regimen Specific Complications
The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- Haematological effects: Administration of plerixafor in conjunction with G-CSF increases circulating leukocytes as well as haematopoietic stem cell populations. White blood cell counts should be monitored during plerixafor therapy. Clinical judgment should be exercised when administering plerixafor to patients with peripheral blood neutrophil counts above 50 x 10⁹ /L. Thrombocytopenia is a known complication of apheresis and has been observed in patients receiving plerixafor. Platelet counts should be monitored in all patients receiving plerixafor and undergoing apheresis.

- Allergic reactions: Plerixafor has been uncommonly associated with potential systemic reactions related to subcutaneous injection such as urticaria, periorbital swelling, dyspnoea, or hypoxia. Symptoms responded to treatments (e.g., antihistamines, corticosteroids, hydration or supplemental oxygen) or resolved spontaneously. Cases of anaphylactic reactions, including
anaphylactic shock, have been reported from world-wide post-marketing experience. Appropriate precautions should be taken because of the potential for these reactions.

- **Spleen size:** The effect of plerixafor on spleen size in patients has not been specifically evaluated in clinical studies. Cases of splenic enlargement and/or rupture have been reported following the administration of plerixafor in conjunction with growth factor G-CSF. Individuals receiving plerixafor in conjunction with G-CSF who report left upper abdominal pain and/or scapular or shoulder pain should be evaluated for splenic integrity.

- Other adverse effects include gastrointestinal symptoms such as nausea, flatulence and vomiting, headache, arthralgia, dizziness and insomnia (patients should be advised against driving).

**DRUG INTERACTIONS:**

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

**ATC CODE:**
Plerixafor L03AX16

**REFERENCES:**


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

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

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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/