Indication
First line or relapsed hairy cell leukaemia (HCL)

ICD-10 codes
Codes with a prefix C91.40

Regimen details

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 5</td>
<td>Cladribine (LITAK®)</td>
<td>0.14mg/kg</td>
<td>SC</td>
</tr>
<tr>
<td>or</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 to 7</td>
<td>Cladribine (LEUSTAT®)</td>
<td>0.09mg/kg/day</td>
<td>Continuous IV infusion</td>
</tr>
</tbody>
</table>

Note: There are 2 brands of cladribine with different routes of administration as above.

Cycle frequency
Normally once only, may be repeated at 6 months if CR not achieved. Consider adding Rituximab if repeat course indicated.

Number of cycles
Usually once only

Administration

Sub-cutaneous:
The LITAK ® brand must be used. The dose should be administered by SC injection in 2 divided doses/day.

Intravenous:
The LEUSTAT ® brand must be used. The dose is administered in 500mL sodium chloride 0.9% over 24 hours, each day for 7 days (i.e. as a continuous infusion).

Pre-medication
Nil required

Emetogenicity
This regimen has low emetogenic potential.

Additional supportive medication
Allopurinol 300mg (100mg if creatinine clearance <20mL/min) OD for 7 days starting 24 hours prior to chemotherapy. Antiviral, antifungal and PCP prophylaxis as per local policy. To commence on day 7 and to continue for 3 months. Consider G-CSF as per local policy.

Extravasation
Cladribine is neutral (Group 1)
Pre-treatment evaluation

<table>
<thead>
<tr>
<th>Investigation</th>
<th>Validity period</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBC*</td>
<td>7 days</td>
</tr>
<tr>
<td>U+Es (including creatinine)</td>
<td>7 days</td>
</tr>
<tr>
<td>LFT</td>
<td>7 days</td>
</tr>
<tr>
<td>LDH</td>
<td>7 days</td>
</tr>
<tr>
<td>Calcium</td>
<td>7 days</td>
</tr>
<tr>
<td>Magnesium</td>
<td>7 days</td>
</tr>
<tr>
<td>Glucose</td>
<td>7 days</td>
</tr>
<tr>
<td>Group and save</td>
<td>7 days</td>
</tr>
<tr>
<td>Direct Antiglobulin Test (DAT)</td>
<td>Baseline</td>
</tr>
</tbody>
</table>

Other pre-treatment investigations:
Hepatitis B and C and HIV 1 and 2 serology

*FBC weekly for the first 4 weeks and then as clinically indicated.

Inform patient and transfusion laboratory that they will require irradiated blood products for all future transfusions.

Standard limits for administration to go ahead
If blood results not within range, authorisation to administer must be given by prescriber/consultant

<table>
<thead>
<tr>
<th>Investigation</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutrophils</td>
<td>&lt; 1.0 x 10⁹/L</td>
</tr>
<tr>
<td>Platelets</td>
<td>&lt; 75 x 10⁹/L</td>
</tr>
<tr>
<td>CrCl</td>
<td>&gt; 50mL/min</td>
</tr>
<tr>
<td>AST/ALT</td>
<td>&lt; ULN</td>
</tr>
</tbody>
</table>

Dose modifications

- **Haematological toxicity**
  No modifications required.

- **Renal impairment**
  LITAK is contraindicated if CrCl < 50mL/min.
  LEUSTAT should be used with caution if CrCl < 30mL/min.

- **Hepatic impairment**
  LITAK is contra-indicated in moderate to severe liver impairment (Child-Pugh score >6).
  LEUSTAT should be used with caution in liver impairment.

Adverse effects - for full details consult product literature/reference texts

- **Serious side effects**
  Myelosuppression
  Widespread maulo-papular rash
  Neurotoxicity
  Renal impairment
Frequently occurring side effects
Myelosuppression
Fever
Erythematous rash
Constipation, diarrhoea
Fatigue
Cough
Myalgia, arthralgia
Injection site reactions

Other side effects
Headache
Reduced appetite
Dizziness

Significant drug interactions – for full details consult product literature/ reference texts
Corticosteroids have been shown to enhance the risk for severe infections when used in combination with cladribine and should not be given concomitantly with cladribine

Additional comments
Rash most frequently seen when co-trimoxazole given at the same time as the cladribine.

Inform patient and transfusion laboratory that they will require irradiated blood products for all future transfusions. The need for irradiated blood products is indefinite following the administration of fludarabine.

References
- Saven et al; Blood (1998); 92: 1918 – 1926
- Von Rohr, A et al; Annals of Oncology (2002); 13: 1641 – 1649

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