Skin Pathway Group – Pegylated Liposomal Doxorubicin (Caelyx) in Primary Cutaneous T-cell Lymphoma

Indication: Advanced Mycosis Fungoides, Stage IIb-IVa and IVb first and subsequent lines
Other tumour stage and advanced primary cutaneous T cell lymphoma

Caelyx in not licensed for this indication, and therefore use should be in line with individual Trust governance process

Regimen details: Pegylated Liposomal Doxorubicin 20mg/m² IV Day 1 and Day 15 (Caelyx)
For patients with poor performance status: Pegylated Liposomal Doxorubicin 20mg/m² IV Day 1 (Caelyx)

Administration: IV infusion over 60 – 90 minutes
Caelyx dose < 90mg Dilute in 250ml Glucose 5%
Caelyx dose ≥ 90mg Dilute in 500ml Glucose 5%

Caelyx is incompatible with Sodium Chloride. The IV line should be flushed before and after the infusion with Glucose 5%

The initial Caelyx dose should be administered no faster than 1mg/minute, to minimize the risk of infusion reactions. If no infusion reaction occurs with the first dose, subsequent Caelyx infusions may be administered over 1 hour

In those patients who experience an infusion reaction, stop the infusion temporarily until symptoms have cleared with or without further therapy (antihistamines, corticosteroids, adrenaline) and resume treatment, at a slower rate, as follows:
5% of the total dose should be infused slowly over the first 15 minutes
If tolerated, without reaction: may double the infusion rate for the next 15 minutes
If tolerated: complete the infusion over the next hour for a total infusion time of 90 minutes

Frequency: Every 28 days, for 6 to 8 cycles

Pre-medication: Paracetamol / Chlorphenamine / Hydrocortisone

Anti-emetics: Low emetogenicity
Follow Local Anti-emetic Policy

Supportive medication: If required, emollients and Pyridoxine 50mg po TDS for palmar-plantar erythrodysesthesia (PPE) (not scientifically proven)

Extravasation: Non-vesicant

Regular investigations:

Prior to Cycle 1:
- FBC Day 1 (within 14 days)
- LFTs Day 1 (within 14 days)
- U&Es Day 1 (within 14 days)
- MUGA scan In high-risk patients
- ECG Baseline and then periodically as required

Prior to Cycle 1 Day 15 dose and all doses onwards:
- FBC Day 1 and Day 15 (within 72 hours)
- LFTs Day 1 and Day 15 (within 72 hours)
- U&Es Day 1 and Day 15 (within 72 hours)
- Clinical Skin scoring and Imaging Every 2 cycles

Toxicities:
- Myelosuppression, infection, nausea, vomiting, stomatitis mucositis, taste alteration, skin changes, palmar-plantar erythrodysesthesia, hot flashes, backache, photosensitivity, urine discoloration, infusion associated reactions, tiredness, cardiotoxicity.
DOSE MODIFICATIONS

Haematological Toxicity

<table>
<thead>
<tr>
<th>Neutrophils (x 10^9/L)</th>
<th>Platelets (x 10^9/L)</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5 – 1.9 or 75 – 150</td>
<td></td>
<td>Give 100% dose</td>
</tr>
<tr>
<td>0.5 – 1.4 or 25 – 74</td>
<td></td>
<td>Delay treatment until neutrophils ≥ 1.5 x 10^9/L and platelets ≥ 75 x 10^9/L, then give 100% dose</td>
</tr>
<tr>
<td>&lt; 0.5 or &lt; 25</td>
<td></td>
<td>Delay treatment until neutrophils ≥ 1.5 x 10^9/L and platelets ≥ 75 x 10^9/L, then give 75% dose</td>
</tr>
</tbody>
</table>

Non-haematological Toxicities

Renal Impairment

No dose reduction needed

Hepatic Impairment

<table>
<thead>
<tr>
<th>Bilirubin (micromol/L)</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 – 51</td>
<td>Give 75%</td>
</tr>
<tr>
<td>≥ 51</td>
<td>Give 50%</td>
</tr>
</tbody>
</table>

Dose modifications for other toxicities

The following measures may help to minimise the risk of PPE for the first 4 – 7 days after Caelyx infusion:

- Keep hands and feet as cool as possible
- Do not wear tight fitting gloves or socks and avoid wearing tight-fitting footwear and high heeled shoes
- Avoid exposing the skin to very hot water, such as the bath or washing up
- Do not rub the skin vigorously or use abrasive washcloths. Pat skin dry after washing
- Avoid the use of topical anaesthetics as they can worsen skin reactions

Disclaimer: The Joint Delivery Chemotherapy Nurse (Oncology Pharmaceuticals) Group is a sub-group of the Medicines & Chemotherapy Steering Group (MCSG) working within the London Cancer Alliance Integrated Cancer System (LCA). The output of the LCA MCSG includes documentation that can be adopted by healthcare organisations at their discretion. It is the responsibility of each individual organisation to ensure that appropriate governance and safety clearance procedures within their own clinical service have been followed prior to implementation of any such pieces of work. LCA assume no responsibility for this process within individual organisations, and no responsibility for the clinical management of individual patients or patient groups. Any clinical queries regarding individual patients or documentation should be directed to the relevant clinical team within the most appropriate healthcare organisation.
### TOXICITY GRADE

<table>
<thead>
<tr>
<th>PALMAR-PLANTAR ERYTHRODYSESTHESIA</th>
<th>STOMATITIS</th>
<th>WEEK 4 After Prior Caelyx Dose</th>
<th>WEEK 5 After Prior Caelyx Dose</th>
<th>WEEK 6 After Prior Caelyx Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Mild erythema, swelling or Desquamation not interfering with ADL</td>
<td>Painless ulcers, erythema or mild soreness</td>
<td><strong>Redose unless</strong> patient experienced a previous Grade 3 or 4 toxicity, in which case wait an additional week</td>
<td><strong>Redose unless</strong> patient experienced a previous Grade 3 or 4 toxicity, in which case wait an additional week</td>
<td><strong>Give 75% dose and return to 4 week interval or stop treatment-discuss with Consultant</strong></td>
</tr>
<tr>
<td><strong>2</strong> Erythema, desquamation or swelling interfering with but not precluding normal physical activities; small blisters or ulcerations &lt; 2cm in diameter</td>
<td>Painful erythema, oedema or ulcers, but can eat</td>
<td><strong>Wait an additional week</strong></td>
<td><strong>Wait an additional week</strong></td>
<td><strong>Give 75% dose and return to 4 week interval or stop treatment-discuss with Consultant</strong></td>
</tr>
<tr>
<td><strong>3</strong> Blistering, ulceration or swelling interfering with walking or normal daily activities; cannot wear usual clothing</td>
<td>Painful erythema, oedema or ulcers, but cannot eat</td>
<td><strong>Wait an additional week</strong></td>
<td><strong>Wait an additional week</strong></td>
<td><strong>No further treatment</strong></td>
</tr>
<tr>
<td><strong>4</strong> Diffuse or local process causing infectious complications, or a bedridden state or hospitalisation</td>
<td>Requires parenteral or enteral support</td>
<td><strong>Wait an additional week</strong></td>
<td><strong>Wait an additional week</strong></td>
<td><strong>No further treatment</strong></td>
</tr>
</tbody>
</table>

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**Location of regimen delivery:**

**Day case setting delivery:**

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**Version:** 1.0  
**Supersedes:** all other versions  
**Approved by LCA Skin Pathway Chemotherapy Lead:** Mark Harries  
**Reason for Update:** LCA Protocol Development  
**Approved by LCA Joint Delivery Subgroup Co-Chairs:** Pauline McCalla & Rebecca Johl  
**Prepared by:** Ravi Shaunak  
**Approved by LCA Medicines & Chemotherapy Steering Group Chair:**  
**Second check by:** Sanna Eestila  
**Date prepared:** January 2015  
**Review Date:** January 2017

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Comments:

Maximum cumulative dose Caelyx = 450mg/m²
A baseline MUGA scan or Echocardiogram should be performed where the patient is considered at risk of having impaired cardiac function e.g. significant cardiac history, hypertension, diabetes, obese, smoker, elderly, previous exposure to anthracyclines, previous thoracic radiotherapy.
MUGA scan or Echocardiogram should be repeated if there is suspicion of cardiac toxicity at any point during treatment, or if cumulative anthracycline dose approaches maximum

Drug interactions:

- Ciclosporin (high dose) increase Caelyx serum levels and myelotoxicity
- Concomitant use of other cardioactive compounds e.g. calcium channel blockers require monitoring of cardiac function throughout treatment
- Phenytoin: reduced blood levels of the anticonvulsant and increased seizure activity
- Warfarin: the anticoagulant effect is increased

References:

Wollina U et al. Multicentre study of Pegylated Liposomal Doxorubicin in patients with cutaneous T cell Lymphoma. Cancer 2003; Sep 1; Vol 98; n5 9 993 – 1001
EORTC Cutaneous Lymphoma Task Force. Phase II clinical trial with Caelyx mono-chemotherapy in patients with advanced Mycosis fungoides stage IIb, Iva and IVb with or without previous chemotherapy. EORTC protocol 21012. Version 1.2 / 26 January, 2005