

**Regimen Monograph**

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**A - Regimen Name**

# PGLDX Regimen

Pegylated Liposomal DOXOrubicin

**Disease Site** Sarcoma  
Kaposi's Sarcoma

**Intent** Palliative

**Regimen Category** **Evidence-Informed :**

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

**Rationale and Uses** Standard therapy for the treatment of HIV-positive Kaposi's sarcoma

**Supplementary Public Funding** [pegylated liposomal DOXOrubicin](#)  
New Drug Funding Program (Liposomal Doxorubicin - HIV-positive Kaposi's Sarcoma) ([NDFP Website](#) )

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**B - Drug Regimen**[pegylated liposomal DOXOrubicin](#)20 mg /m<sup>2</sup>

IV

Day 1

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Until disease progression or unacceptable toxicity.

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Doses should be modified according to the protocol by which the patient is being treated.

**Dosage with toxicity**

<b>Worst Toxicity &amp; Toxicity on day of planned dosing</b>	<b>Action*: Week 3</b>	<b>Action*: Week 4</b>
Grade 1 skin	If was ≥grade 3, delay for 1 week; otherwise treat on time	If still grade 1, ↓ dose by 25%
Grade 1 stomatitis	Treat on time with no dose modification	Not applicable

Grade 2 skin	Delay for 1 week	If still grade 2, ↓ dose by 50% If grade 1, ↓ dose by 25%
Grade 2 stomatitis	Delay for 1 week	If still grade 2, ↓ dose by 25%
Grade 3 skin	Delay for 1 week	If still grade 3, discontinue If grade 2, then ↓ dose by 50% If grade 1, ↓ dose by 25%
Grade 3 stomatitis	Delay for 1 week	If improved, ↓ dose by 25%
Grade 4 skin	Delay for 1 week	If still ≥ grade 3, discontinue If ≤ grade 2, ↓ dose by 50%
Grade 4 stomatitis	Delay for 1 week	If still grade 4, discontinue If improved, ↓ dose by 50%
Grade 3 myelosuppression	↓ dose by 25%	
Grade 4 ANC, platelets, febrile neutropenia or thrombocytopenic bleeding	↓ dose by 50%	
Significant cardiotoxicity	Discontinue	
Grade 3 other	↓ dose by 25%	
Grade 4 other	Discontinue or ↓ dose by 50%	
*Do not retreat until ANC > 1 x 10 <sup>9</sup> /L, platelets > 50-100 x 10 <sup>9</sup> /L and other toxicity ≤ grade 2 / or as indicated above		

**Management of Infusion-related reactions with Anthracyclines:**

Also refer to the CCO guideline for detailed description of [Management of Cancer Medication-Related Infusion Reactions](#).

Grade	Management	Re-challenge
1 or 2	<ul style="list-style-type: none"> <li>• Stop or slow the infusion rate.</li> <li>• Manage the symptoms.</li> </ul>	<ul style="list-style-type: none"> <li>• Consider pre-medications and administering at a slower infusion rate.</li> </ul>
3 or 4	<ul style="list-style-type: none"> <li>• Stop treatment.</li> <li>• Aggressively</li> </ul>	<ul style="list-style-type: none"> <li>• Re-challenge is discouraged, especially if vital signs have been affected.</li> </ul>

	manage symptoms.	<ul style="list-style-type: none"> <li>Consider desensitization if therapy is necessary.</li> </ul>
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### **Hepatic Impairment**

<b>Bilirubin (<math>\mu\text{mol/L}</math>)</b>	<b>% Standard Dose (any cycle)</b>
21-51	50%
>51	25%

### **Renal Impairment**

No modifications are necessary for mild to moderate renal impairment (creatinine clearance > 30 mL/min). No studies have been done in patients with severe renal impairment.

### **Dosage in the Elderly**

Limited information in patients  $\geq$  60 years. Use with caution.

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## F - Adverse Effects

Refer to [pegylated liposomal DOXOrubicin](#) drug monograph(s) for additional details of adverse effects

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
<ul style="list-style-type: none"> <li>• Myelosuppression ± infection/bleeding (may be severe)</li> <li>• Palmar-plantar erythrodysesthesia (Hand-foot syndrome)</li> <li>• Stomatitis</li> <li>• Fatigue</li> <li>• Acute Hypersensitivity reactions (first infusion)</li> <li>• Nausea and vomiting</li> <li>• Rash (may be severe)</li> <li>• Alopecia</li> <li>• Anorexia</li> </ul>	<ul style="list-style-type: none"> <li>• Arterial, venous thromboembolism</li> <li>• Secondary malignancy</li> <li>• Cardiotoxicity</li> <li>• Phlebitis</li> </ul>

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## G - Interactions

Refer to [pegylated liposomal DOXOrubicin](#) drug monograph(s) for additional details

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## H - Drug Administration and Special Precautions

Refer to [pegylated liposomal DOXOrubicin](#) drug monograph(s) for additional details

### Administration:

Pegylated liposomal doxorubicin must **not** be given by the intramuscular or subcutaneous route.

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- For dose < 90mg, dilute drug in 250mL D5W.
  - For dose ≥ 90mg, dilute drug in 500mL D5W.
  - Only use 5% Dextrose solution for further dilution. Use of other diluents or ones containing bacteriostatic agents (i.e. benzyl alcohol) may cause drug precipitation.
  - Do not administer as a bolus injection or undiluted solution. The Caelyx® infusion line can be connected through the side port of a 5% Dextrose infusion for further diluent, or to minimize risk of thrombosis or extravasation.
  - Do not use in-line filters. Do not admix with other drugs.
  - To minimize the risk of infusion reactions, the initial dose is administered at a rate no greater than 1 mg/minute. If no infusion reaction is observed, subsequent infusions may be administered over 30 minutes (for Kaposi's sarcoma patients).
  - The following graduated rate was used for patients who experienced an infusion reaction in the breast clinical trial: 5% of the total dose infused IV over 15 minutes. If tolerated, 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.
  - Avoid extravasation. It may occur with or without an accompanying stinging or burning sensation, and even if blood returns well on aspiration of the infusion needle. If any signs or symptoms of extravasation occur, the injection or infusion should be immediately terminated and restarted in another vein. Any known or suspected extravasation should be managed promptly.

Also refer to the CCO guideline for detailed description of [Management of Cancer Medication-Related Infusion Reactions](#).

#### Contraindications:

- patients who have a history of hypersensitivity reactions to a conventional formulation of doxorubicin, other anthracyclines, anthracenediones, or components of the pegylated liposome
- patients with Kaposi's Sarcoma and HIV who have had splenectomy (no experience)

#### Other Warnings/ Precautions:

- use with caution in patients with a history of cardiovascular disease and/or prior anthracycline use
- care should be exercised in patients with diabetes as the infusate is dextrose water
- pegylated liposomal doxorubicin (Caelyx) is a unique formulation of doxorubicin and should never be used interchangeably with other formulations of doxorubicin

#### Pregnancy and Lactation:

- Pegylated liposomal doxorubicin is not recommended for use in pregnancy. Adequate contraception should be used by both sexes during treatment, and for at least **6 months** after the last dose.
- Pegylated liposomal doxorubicin is contraindicated in breastfeeding.

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## I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

### Recommended Clinical Monitoring

- Cardiac function tests (Echo, RNA and/or MUGA scans) for all patients with cardiac risk factors; baseline and as clinically indicated. Regular cardiac function tests before each additional dose over the cumulative dose threshold of 450 mg/m<sup>2</sup>. (Cumulative dose lower for high risk patients.)
- CBC; baseline and before each cycle
- Liver function tests; baseline and at each visit
- Clinical toxicity assessment for stomatitis, rash, hand-foot syndrome, hypersensitivity, infection, bleeding and cardiac symptoms; at each visit
- Grade toxicity using the current [NCI-CTCAE \(Common Terminology Criteria for Adverse Events\) version](#)

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## J - Administrative Information

Approximate Patient Visit	1 hour
Pharmacy Workload (average time per visit)	19.371 minutes
Nursing Workload (average time per visit)	39.167 minutes

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## K - References

Pegylated liposomal doxorubicin drug monograph, Cancer Care Ontario.

Gill PS, Wernz J, Scadden DT, et al. Randomized phase III trial of liposomal daunorubicin versus doxorubicin, bleomycin, and vincristine in AIDS-related Kaposi's sarcoma. *J Clin Oncol* 1996;14:2353-64.

Northfelt DW, Dezube B, Miller B, et al. Randomized comparative trial of Doxil vs. Adriamycin, bleomycin, and vincristine (ABV) in the treatment of severe AIDS-related Kaposi's sarcoma (AIDS-KS) [abstract no. 1515]. *Blood* 1995; 86(10) suppl. 1: 382a

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Osoba D, Northfelt DW, Budd DW et al. Effect of treatment on health-related quality of life in acquired immunodeficiency syndrome (AIDS)-related Kaposi's sarcoma: a randomized trial of pegylated –liposomal doxorubicin versus doxorubicin, bleomycin, and vincristine. *Cancer Investigation* 2001;19(6):573-80.

Stewart JSW, Jablonowski H, Goebel FD, et al. Randomized comparative trial of pegylated liposomal doxorubicin versus bleomycin and vincristine in the treatment of AIDS-related Kaposi's sarcoma. International Pegylated Liposomal Doxorubicin Study Group. *J Clin Oncol* 1998;16(2):683-91.

**May 2022** Re-linked NDFP form

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## M - Disclaimer

### **Regimen Abstracts**

*A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.*

*Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.*

### **Regimen Monographs**

*Refer to the [New Drug Funding Program](#) or [Ontario Public Drug Programs](#) websites for the most up-to-date public funding information.*

*The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.*

*The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended*



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*that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.*

*Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.*

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