

Regimen Monograph

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A - Regimen Name

CYCLTOPO Regimen

Topotecan-Cyclophosphamide

Disease Site Sarcoma - Ewing's
Sarcoma - Soft Tissue

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.

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B - Drug Regimen

cyclophosphamide	250 mg /m ²	IV	Days 1 to 5
topotecan	0.75 mg /m ²	IV	Days 1 to 5

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C - Cycle Frequency**REPEAT EVERY 21 DAYS**

Until disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate

Other Supportive Care:

- Consider prophylactic growth factor support (according to local practice) especially for heavily pretreated patients.
- Ensure patient receives appropriate PO/IV hydration.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. The following recommendations are in use at some centres.

Dosage with toxicity**Hematologic Toxicities**

<u>Toxicity</u>	<u>Topotecan (% previous dose)*</u>	<u>Cyclophosphamide (% previous dose)*</u>
Grade 4 neutropenia \geq 7 days, or Febrile neutropenia, or Previous delay due to neutropenia	↓ 20%	↓ 20%
Platelets \leq 25 X 10 ⁹ /L or bleeding	↓ 20%	↓ 20%
Grade 3 non-hematological toxicities	↓ 20%	↓ 20%
Grade 4 non-hematological toxicities	Discontinue	Discontinue
Cystitis	No change	Consider dose reduction

*Do not retreat until major organ toxicities \leq grade 2, neutrophils \geq 1.5 X 10⁹/L; platelets \geq 100 X 10⁹/L, and hemoglobin \geq 90 g/L (after transfusion if necessary).

Hepatic Impairment

<u>Topotecan</u>	<u>Cyclophosphamide</u>
No adjustments required for bilirubin < 171 μ mol/L	No adjustments required

Renal Impairment

<u>Creatinine Clearance (mL/min)</u>	<u>Topotecan (% previous dose)</u>	<u>Cyclophosphamide (% previous dose)</u>
>40	100%	100%
>30-40	50%	
20-30		DISCONTINUE
10-<20	DISCONTINUE	50% or OMIT
<10		

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F - Adverse Effects

Refer to [cyclophosphamide](#), [topotecan](#) 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"> • Myelosuppression ± infection and bleeding (may be severe) • Alopecia • Diarrhea (may be severe) • Constipation, abdominal pain • Mucositis • Nausea and vomiting • Dyspnea/cough (may be severe) • Anorexia • Headache, pain • Rash (may be severe) • Fatigue 	<ul style="list-style-type: none"> • Hypersensitivity • GI obstruction • Pneumonitis • ↑ LFTs • Arterial/venous thromboembolism • Cardiotoxicity • ↑ QTc • Nephrotoxicity, SIADH • Pancreatitis • Tumour lysis syndrome • Secondary malignancies • Cystitis

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G - Interactions

Refer to [cyclophosphamide](#), [topotecan](#) drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to [cyclophosphamide](#), [topotecan](#) drug monograph(s) for additional details

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I - Recommended Clinical Monitoring

Recommended Clinical Monitoring

- Baseline and regular CBC – counts must be assessed prior to each cycle.
- Clinical toxicity assessment of infection GI, pulmonary, dermatologic, GU effects.
- Baseline and regular hepatic and renal function tests and urinalysis
- Grade toxicity using the current [NCI-CTCAE \(Common Terminology Criteria for Adverse Events\) version](#)

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J - Administrative Information

Approximate Patient Visit	2 hours
Pharmacy Workload (average time per visit)	24.841 minutes
Nursing Workload (average time per visit)	41.667 minutes

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K - References

Hunold A, Weddeling N, Paulussen M, et al. Topotecan and cyclophosphamide in patients with refractory or relapsed Ewing tumors. *Pediatric Blood & Cancer* 2006; 47: 795–800.

Saylors RL, Stine KC, Sullivan J, et al. Cyclophosphamide plus topotecan in children With recurrent or refractory solid tumors: A Pediatric Oncology Group Phase II Study. *J Clin Oncol* 2001; 19: 3463-9.

June 2021 removed "unfunded" flag for topotecan

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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.

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