Regimen Monograph

A - Regimen Name

TOPO Regimen

Topotecan

Disease Site	Lung Small Cell
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	Treatment of relapsed small cell lung cancer in patients whose disease is likely to be chemosensitive (≥ 60 days from last dose of chemotherapy).

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B - Drug Regimen

topotecan	1.5 mg /m²	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: Low

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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.

Prior to administration of the first course of topotecan, patients must have a baseline neutrophil count of ≥ 1.5 x 10^9/L, a platelet count of > 100 x 10^9/L, and a hemoglobin level of ≥90 g/L.

Dosage with toxicity

Dose levels: 1.5 mg/m^2, 1.25 mg/m^2, 1 mg/m^2

Worst Toxicity Previous Cycle	Action[1]
Grade 4 neutropenia ≥ 7 days	Reduce dose by 1 dose level OR Use G-CSF with next cycle
Febrile neutropenia	
Cycle delay for hematologic toxicity	
Platelets <25 x 10^9/L	Reduce dose by 1 dose level
Grade 3 GI or organ toxicity	
Symptoms suggestive of pneumonitis	Hold and manage patient appropriately. Discontinue if confirmed.
Grade 4 GI or organ toxicity	Discontinue
1. Do not retreat until neutrophils ≥ 1 x 10^9/L, platelets ≥ 100 x 10^9/L, hemoglobin ≥90 g/L (after transfusion if necessary) and other toxicity ≤ grade 2.	

Hepatic Impairment

No dosage adjustment is required for treating patients with bilirubin < 171 µmol/L. Total topotecan clearance in patients with hepatic impairment only decreased by about 10%, as compared to the control group of patients.

Renal Impairment

Creatinine Clearance (mL/min)	% Usual dose
20 – 39	**REDUCE** Topotecan to **50 %** dose
< 20	**CONTRAINDICATED**

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F - Adverse Effects

Refer to 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
• 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	• Hypersensitivity • GI obstruction • Pneumonitis • ↑ LFTs

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G - Interactions

Refer to topotecan drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to topotecan drug monograph(s) for additional details

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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

- CBC; baseline and regular (must be assessed prior to each cycle)
- Liver and kidney function tests; baseline and regular
- Clinical toxicity assessment of GI, skin, infection, bleeding and pulmonary effects; 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	0.5 hour
Pharmacy Workload (average time per visit)	9.692 minutes
Nursing Workload (average time per visit)	36.667 minutes

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K - References

Eckardt JR, von Pawel J, Pujol JL, et al. Phase III study of oral compared with intravenous topotecan as second-line therapy in small-cell lung cancer. J Clin Oncol 2007;25:2086-92.

O'Brien MER, Ciuleanu TE, Hristo T, et al. Phase III trial comparing supportive care alone with supportive care with oral topotecan in patients with relapsed small-cell lung cancer. J Clin Oncol 2006;24:5441-47.

Topotecan drug monograph, Cancer Care Ontario.

von Pawel J, Schiller JH, Shepherd FA, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. J Clin Oncol. 1999;17(2):658-67.

PEBC Advice Documents or Guidelines

- Systemic Therapy for Small-Cell Lung Cancer: ASCO-OH(CCO) Guideline

November 2023 Updated PEBC guideline link

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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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