Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Dose Modifications | Adverse Effects | Interactions | Drug Administration and Special Precautions | Recommended Clinical Monitoring | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

ALEC Regimen

Alectinib

Disease Site

Lung
Non-Small Cell

Intent

Adjuvant

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

Monotherapy in patients with completely resected, anaplastic lymphoma kinase (ALK) mutated, non-small cell lung cancer (NSCLC), confirmed post-operatively as being stage IB (tumour size of ≥4 cm) to stage IIIA (per AJCC 7th edition, or equivalent).

Refer to EAP criteria for full funding details.

Supplementary Public Funding

alectinib
Exceptional Access Program (alectinib - Adjuvant treatment of ALK-positive non-small cell lung cancer, according to specific criteria)

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B - Drug Regimen

Patients must have documented ALK-positive status, based on a validated ALK assay, prior to starting treatment with alectinib.

alectinib	600 mg	PO	BID

Start alectinib within 6 to 12 weeks post-operatively, following complete surgical resection, if adjuvant chemotherapy was not used.

Start alectinib within 26 weeks of surgical resection if adjuvant chemotherapy was administered.

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C - Cycle Frequency

CONTINUOUS TREATMENT

Up to a maximum of 2 years, unless disease progression or unacceptable toxicity.

Refer to the EAP criteria for details on retreatment.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low – No routine prophylaxis; PRN recommended

- Also refer to CCO Antiemetic Recommendations.

Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the hepatitis B virus screening and management guideline.

Other Supportive Care:

- Patients must avoid sun exposure while on treatment and for at least 7 days after the last dose, and must use UVA/B sunscreen and lip balm (at least SPF 50).

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E - Dose Modifications

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

Dosage with toxicity

Dose Level	Dose (mg) BID
Starting Dose	600
- 1	450
- 2	300
-3	Discontinue

Toxicity	Action
GI perforation	Discontinue.
ILD/pneumonitis of any Grade	Hold; if confirmed, discontinue.
Grade 3 Renal Impairment	Hold until serum creatinine recovers to baseline or ≤ Grade 1, then resume at 1 dose level ↓.
Grade 4 Renal Impairment	Discontinue.
≥ Grade 3 ALT or AST elevation (> 5 x ULN) **and** Total bilirubin ≤ 2 x ULN	Hold until recovery to baseline, OR AST or ALT ≤ 3 x ULN. Resume at 1 dose level ↓.
≥ Grade 2 ALT or AST elevation (> 3 x ULN) **and** Total bilirubin ≥ 2 x ULN (in absence of cholestasis or hemolysis)	Discontinue.
Grade 2 to 3 Bradycardia (HR < 60 bpm) (symptomatic)	Hold until recovery to ≤ Grade 1 (asymptomatic) bradycardia or HR of ≥ 60 bpm. Evaluate concomitant medications; if contributing, discontinue or reduce dose of concomitant drug. Resume at previous dose. If no concomitant medication contributing, or contributing medication not stopped/reduced: resume at 1 dose level ↓

Grade 4 Bradycardia (HR < 60 bpm) (life-threatening consequences, urgent intervention required)	Discontinue if no contributing concomitant medication. If contributing concomitant medication is discontinued or reduced: Hold until recovery to ≤ Grade 1 (asymptomatic) bradycardia or HR of ≥ 60 bpm, with frequent monitoring. Resume at 1 dose level ↓. If recurs: discontinue.
CPK elevation > 5 x ULN	Hold until recovery to baseline or ≤ 2.5 x ULN; resume at same dose.
CPK elevation > 10 x ULN **or** 2nd Occurrence of CPK elevation > 5 x ULN	Hold until recovery to baseline or ≤ 2.5 x ULN; resume at 1 dose level ↓.
Hemolytic anemia with hemoglobin of < 100 g/L (≥ Grade 2)	Hold until recovery, then resume at 1 dose level ↓. OR Discontinue.

Hepatic Impairment

Clinical trials only included patients with adequate hepatic function (AST and ALT ≤ 2.5 x ULN [or ≤ 5 x ULN in patients with liver metastases at baseline], and bilirubin ≤ 34 micromol/L).

Hepatic impairment	Alectinib Dose
Mild or Moderate	No dose adjustment required. Monitor liver function closely.
Severe	450 mg twice daily. Monitor liver function closely.

Renal Impairment

Creatinine Clearance (mL/min)	Alectinib Dose
≥ 30	No dose adjustment required
< 30	Not been studied

Dosage in the Elderly

No dose adjustment required. Efficacy appeared to be consistent between patients aged ≥ 65 years and younger patients. Serious adverse events, including events leading to discontinuation, were more frequent in patients aged ≥ 65 years compared to younger patients.

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F - Adverse Effects

Refer to alectinib drug monograph(s) for additional details of adverse effects.

Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• ↑ CPK • Constipation • ↑ LFTs (may be severe) • Musculoskeletal pain • Fatigue	• Anemia • Rash • Edema • Creatinine increased • Nausea, vomiting • Diarrhea • Weight gain • Dysgeusia • Bradycardia • Hyperuricemia	• Photosensitivity • Visual disorders • Atrioventricular block • QT interval prolonged • Venous thromboembolism • Drug-induced liver injury • Nephrotoxicity • Pneumonitis / eosinophilic pneumonia • GI perforation • Hemolytic anemia

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G - Interactions

Refer to alectinib drug monograph(s) for additional details.

- Avoid concomitant use of drugs that lower the heart rate or prolong PR interval, if possible, due to additive effects.

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H - Drug Administration and Special Precautions

Refer to alectinib drug monograph(s) for additional details.

Administration

- Alectinib should be swallowed whole with food.
- Capsules should not be opened or dissolved.
- If a dose is missed the next dose should be taken at the next scheduled time.
- If vomiting occurs after taking a dose, a repeat dose should not be taken; the next dose should be taken at the next scheduled time.
- Caution with grapefruit, grapefruit juice, products with grapefruit extract, star fruit, Seville oranges, pomegranate, and other similar fruits that inhibit CYP3A4 during alectinib treatment due to risk for increased toxicity.
- Store between 15-30ºC in the original package.

Contraindications

- Patients who have a hypersensitivity to this drug or any of its components

Warnings/Precautions

- Use with caution in patients who are at risk for gastrointestinal perforation (e.g. concomitant use of medications with GI perforation risk, history of diverticulitis, metastases to the GI tract).
- Use with caution in patients with hepatic impairment or renal impairment.
- Use with caution in patients who have bradycardia at baseline (< 60 bpm), a history of syncope or arrhythmia, sick sinus syndrome, sinoatrial block, AV block, ischemic heart disease, CHF or who are on medications that lower HR.
- Vision disorders and dizziness have been reported. Patients with these symptoms should use caution when driving or operating machines.
- Contains lactose; carefully consider use in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.

Pregnancy/Lactation

- This regimen is not recommended for use in pregnancy. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is not recommended during this treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).
- Effects on fertility: No information available

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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.

Refer to the hepatitis B virus screening and management guideline for monitoring during and after treatment.

Recommended Clinical Monitoring

- CBC; Baseline, at each visit, and as clinically indicated, or if hemolytic anemia suspected
- Liver function tests; Baseline, every 2 weeks during the first 3 months of treatment, then at each visit or as clinically indicated; more frequent with abnormal LFTs.
- Renal function tests; Baseline, at each visit, and as clinically indicated
- Blood CPK levels; Baseline, every 2 weeks for the first month, and as clinically indicated
- Electrolytes, including serum calcium and potassium; Baseline, at each visit, and as clinically indicated
- Blood pressure and heart rate; Baseline, at each visit, and as clinically indicated.
- ECG; Baseline, and as clinically indicated to evaluate QTc, AV block.
- Clinical toxicity assessment for photosensitivity, rash, edema, fatigue, myalgia, dizziness, headache, visual disorders, respiratory and GI 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

Outpatient prescription for home administration

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K - References

Alectinib drug monograph, Ontario Health (Cancer Care Ontario).

CDA reimbursement recommendation: alectinib. Canadian Journal of Health Technologies 2024;4(11).

Wu YL, Dziadziuszko R, Ahn JS, et al. Alectinib in resected ALK-positive non-small-cell lung cancer. N Engl J Med 2024 Apr 11;390(14):1265-1276. doi: 10.1056/NEJMoa2310532.

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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.

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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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