Regimen Monograph

Regimen NameDrug RegimenCycle FrequencyPremedication and Supportive MeasuresDose ModificationsAdverseEffectsInteractionsDrug Administration and Special PrecautionsRecommended Clinical MonitoringAdministrativeInformationReferencesOther NotesDisclaimer

A - Regimen Name

LAZE+AMIV Regimen			
Disease Site	Lung Non-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.		
	This 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). 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.		
Rationale and Uses	First-line treatment of locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations		

back to top

B - Drug Regimen				
Cycle 1:				
amivantamab ¹	350 mg	IV	Day 1	
(This drug is not currently publicly funded for this regimen and intent)				
amivantamab ¹	700 mg	IV	Day 2	
(This drug is not currently publicly funded for this regimen and intent)				
¹ Use split dosing of 350 mg on day 1 and 1050 mg on day 2, for body weight at baseline \ge 80 kg.				
amivantamab ²	1050 mg	IV	Days 8, 15, 22	
(This drug is not currently publicly funded for this regimen and intent)				
² Use 1400 mg for body weight at baseline \geq 80 kg.				
lazertinib	240 mg	PO	Days 1 to 28	
Cycle 2 and beyond:				
amivantamab ²	1050 mg	IV	Days 1, 15	
(This drug is not currently publicly funded for this regimen and intent)				
² Use 1400 mg for body weight at baseline \geq 80 kg.				
lazertinib	240 mg	PO	Days 1 to 28	
(This drug is not currently publicly funded for this regimen and intent)				

The product monograph recommends administering amivantamab via peripheral line for the first 4 weeks of treatment, to reduce the risk of infusion-related reactions. If peripheral access is limiting, may consider the use of a central line starting after Cycle 1, day 8, if deemed medically acceptable.

back to top

C - Cycle Frequency

REPEAT EVERY 28 DAYS

Until disease progression or unacceptable toxicity

back to top

D - Premedication and Supportive Measures

Antiemetic Regimen:	Low (amivantamab)
	Low – No routine prophylaxis; PRN recommended (lazertinib)

• Also refer to <u>CCO Antiemetic Recommendations</u>.

Other Supportive Care:

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

Amivantamab Pre-medications (prophylaxis for infusion reaction (IR)):

Cycle 1, Days 1 and 2:

- Dexamethasone 20 mg IV (or equivalent) 45-60 minutes pre-infusion on day 1
- Dexamethasone <u>10 mg</u> IV (or equivalent) 45-60 minutes pre-infusion on <u>day 2</u>
- Acetaminophen 650-1000 mg PO 30-60 minutes pre-infusion on both days
- Diphenhydramine 25-50 mg IV (or equivalent) 15-30 minutes pre-infusion (or PO 30-60 minutes pre-infusion) on both days

Subsequent Doses:

- Acetaminophen 650-1000 mg PO 30-60 minutes pre-infusion
- Diphenhydramine 25-50 mg IV (or equivalent) 15-30 minutes pre-infusion (or PO 30-60 minutes pre-infusion)
- Optional Dexamethasone 10 mg IV (or equivalent) 45-60 minutes pre-infusion (may be considered for patients who had an IR on Cycle 1, Day 1 or Day 2).

back to top

K - References

Cho BC, Lu S, Felip E, et al. Amivantamab plus lazertinib in previously untreated *EGFR*-mutated advanced NSCLC. N Engl J Med 2024;391(16):1486-98. doi: 10.1056/NEJMoa2403614.

Prescribing information: Amivantamab (Rybrevant). Janssen Biotech Inc. (USA), September 2024.

Product monograph: Amivantamab (Rybrevant). Janssen Inc., June 28, 2024.

Product monograph: Lazertinib (Lazcluze). Janssen Inc., March 6, 2025.

Reimbursement recommendation (draft): lazertinib and amivantamab. Canada's Drug Agency (CDA). June 2025.

July 2025 new ST-QBP regimen

back to top

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 <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> 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 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.

While care has been taken in the preparation of the information contained in the Formulary, 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.

CCO and the Formulary's content providers shall have no liability, whether direct, indirect, consequential, contingent, special, or incidental, related to or arising from the information in the Formulary or its use thereof, whether based on breach of contract or tort (including negligence), and even if advised of the possibility thereof. Anyone using the information in the Formulary does so at his or her own risk, and by using such information, agrees to indemnify CCO and its content providers from any and all liability, loss, damages, costs and expenses (including legal fees and expenses) arising from such person's use of the information in the Formulary.

back to top