

Regimen Monograph

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A - Regimen Name

ATEZ Regimen

Atezolizumab

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 Adjuvant treatment for patients with completely resected stage II or III non-small cell lung cancer (NSCLC)*, with no disease progression after adjuvant platinum-based chemotherapy, and have good performance status

*excluding T2bN0. Tumours must have PD-L1 expression on $\geq 50\%$ of tumour cells and have no EGFR or ALK genomic aberrations.

Supplementary Public Funding [atezolizumab](#)
New Drug Funding Program (Atezolizumab - Adjuvant Treatment for Non-Small Cell Lung Cancer) ([NDFP Website](#))

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B - Drug Regimen

Start treatment within 3 to 8 weeks from the completion of chemotherapy.

[atezolizumab](#) 840 mg IV Day 1; every 2 weeks

OR

[atezolizumab](#) 1200 mg IV Day 1; every 3 weeks

OR

[atezolizumab](#) 1680 mg IV Day 1; every 4 weeks

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C - Cycle Frequency

840 mg dosing: Repeat every **2 weeks**

1200 mg dosing: Repeat every **3 weeks**

1680 mg dosing: Repeat every **4 weeks**

Until disease recurrence, unacceptable toxicity, or up to a maximum of 48 weeks*, whichever comes first

(i.e. maximum of 12 cycles every 4 weeks, 16 cycles every 3 weeks, or 24 cycles every 2 weeks)

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low

- 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.

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E - Dose Modifications

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

Avoid the use of corticosteroids or immunosuppressants before starting treatment.

Dosage with toxicity

- Healthcare professionals should also consult the most recent atezolizumab product monograph for additional information.

Summary of Principles of Management

- Immune-related adverse effects (irAEs) are different in their presentation, onset and duration compared to conventional chemotherapy. Patient and provider education is essential.
- Initial irAE presentation can occur months after completion of treatment and affect multiple organs.
- Dose escalation or reduction is not recommended.
- If no other cause can be identified (such as infection), any new symptom should be considered immune-related and prompt treatment initiated.
- Organ-specific system-based toxicity management is recommended.
- **Refer to CCO's [Immune Checkpoint Inhibitor Toxicity Management Guideline](#) for detailed descriptions of immune-related toxicities and their management.**

Management of Infusion-related reactions:

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"> Stop or slow the infusion rate. Manage the symptoms. <p>Restart:</p> <ul style="list-style-type: none"> No specific recommendations can be made at this time. 	<ul style="list-style-type: none"> Re-challenge with close monitoring. Consider pre-medication with antipyretic and H1-receptor antagonists.
3 or 4	<ul style="list-style-type: none"> Stop treatment. Aggressively manage symptoms. 	<ul style="list-style-type: none"> Permanently discontinue (do not re-challenge).

Hepatic Impairment

Refer to CCO's [Immune Checkpoint Inhibitor Toxicity Management Guideline](#) for management of immune-related hepatic toxicities.

Hepatic Impairment	Atezolizumab Dose
Mild (bilirubin 1 to 1.5 x ULN and any AST, OR bilirubin ≤ ULN and AST > ULN)	No change
Moderate (bilirubin >1.5 to 3 x ULN and any AST)	No change
Severe (bilirubin >3 x ULN and any AST)	No data

Renal Impairment

Refer to CCO's [Immune Checkpoint Inhibitor Toxicity Management Guideline](#) for management of immune-related renal toxicities.

Creatinine Clearance (mL/min)	Atezolizumab Dose
≥ 30	No change
< 30	No data

Dosage in the Elderly

No dose adjustment needed. No differences in safety or efficacy between patients ≥ 65 years of age and younger patients observed. Data in patients > 75 years of age are too limited to draw conclusions.

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F - Adverse Effects

Refer to [atezolizumab](#) 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
<ul style="list-style-type: none"> • Infection (may be severe) • Fatigue 	<ul style="list-style-type: none"> • Rash, pruritus (may be severe) • Anorexia • Musculoskeletal pain • Anemia • Cough, dyspnea • Nausea, vomiting • Constipation • Diarrhea (may be severe) 	<ul style="list-style-type: none"> • Hypo and hyperthyroidism • Type 1 diabetes mellitus • Pneumonitis • Hypersensitivity; infusion reactions • Adrenal insufficiency • Hypophysitis • Meningo-encephalitis • Pancreatitis • Ocular inflammatory disorders • Hepatitis • Neuropathy, myasthenia gravis, Guillain-Barre syndrome • Myelitis • Myositis / rhabdomyolysis • Myocarditis, pericarditis • Venous thromboembolism • Nephritis • Stevens-Johnson syndrome • Toxic epidermal necrolysis • Hemophagocytic lymphohistiocytosis • Autoimmune hemolytic anemia • Vasculitis

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G - Interactions

Refer to [atezolizumab](#) drug monograph(s) for additional details.

- Atezolizumab is not expected to have pharmacokinetic drug-drug interactions as it is not metabolized by drug metabolizing enzymes. No pharmacokinetic drug interaction studies have been performed.
- Use of systemic corticosteroids or immunosuppressants should be avoided prior to starting atezolizumab because of potential interference with efficacy. They can be used to treat immune-mediated reactions after starting the drug.

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H - Drug Administration and Special Precautions

Refer to [atezolizumab](#) drug monograph(s) for additional details.

Administration

- Withdraw required volume of drug concentrate from vial and dilute in 250mL of 0.9% sodium chloride solution (concentration 3.2 to 16.8 mg/mL). Mix by gentle inversion; do not shake.
- Dilute with 0.9% Sodium Chloride Injection only in a polyvinyl chloride (PVC), polyethylene (PE), polyolefin (PO) or polypropylene (PP) infusion bag.
- Do not mix atezolizumab with other medicinal products.
- Compatible with in-line filter membranes composed of polyethersulfone or polysulfone. Compatible with infusion sets and other infusion aids composed of PVC, PE, polybutadiene or polyetherurethane.
- The initial dose must be administered over 60 minutes. If the first infusion is tolerated all subsequent infusions may be administered over 30 minutes. DO NOT administer as an IV push or bolus.
- Do not co-administer other drugs through the same infusion line.
- If a planned dose is missed, it should be administered as soon as possible; do not wait until the next planned dose. The schedule of administration should be adjusted to maintain the prescribed interval between doses, based on the regimen used.
- Store vials at 2-8°; do not freeze. Protect from light.

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

Contraindications

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

Other Warnings/Precautions

- Atezolizumab may cause serious immune-mediated reactions affecting multiple organ systems, including GI, hepatic, respiratory, endocrine and others. Use with caution and monitor closely in patients with pre-existing autoimmune disease and conditions such as colitis, hepatic impairment, respiratory or endocrine disorders, such as hypo or hyperthyroidism or diabetes mellitus.
- Caution in patients who have previously experienced a severe or life-threatening adverse skin reaction on previous treatment with other immune stimulatory anticancer drugs.
- Severe infections have been observed in clinical trials.

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).
- Fertility effects: Likely, especially in females

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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 and Q3-6 weeks, or as clinically indicated
- Liver function tests; Baseline and Q3-6 weeks, or as clinically indicated
- Renal function tests, urine protein; Baseline and Q3-6 weeks, or as clinically indicated
- Thyroid function tests; Baseline, and as clinically indicated
- Blood glucose; Baseline, and as clinically indicated
- Clinical toxicity assessment for infection, fatigue, infusion-related and immune-mediated reactions, such as endocrine, skin, GI, cardiac, neurologic, musculoskeletal, ocular and respiratory toxicity; 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	1.5 hrs (1st visit); 1 hr (subsequent visits)
Pharmacy Workload (average time per visit)	18.6 minutes
Nursing Workload (average time per visit)	40.75 minutes

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K - References

Atezolizumab drug monograph. Ontario Health (Cancer Care Ontario).

CADTH reimbursement recommendation: Atezolizumab (monotherapy for adjuvant treatment following resection and platinum-based chemotherapy for patients with non–small cell lung cancer). September 2022.

Felip E, Altorki N, Zhou C, et al. Adjuvant atezolizumab after adjuvant chemotherapy in resected stage IB-IIIa non-small-cell lung cancer (IMpower010): a randomised, multicentre, open-label, phase 3 trial. *Lancet*. 2021 Oct 9;398(10308):1344-57.

March 2024 Modified Dosage in hepatic impairment, Adverse effects, Drug administration, Pregnancy/lactation and Monitoring sections

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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 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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