Drug Monograph

A - Drug Name

atezolizumab

COMMON TRADE NAME(S): Tecentriq™

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B - Mechanism of Action and Pharmacokinetics

Atezolizumab is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that binds to programmed cell death-ligand 1 (PD-L1) and blocks interactions with the PD-1 and B7.1 receptors on activated T cells. It releases PD-L1/PD-1 pathway-mediated inhibition of the immune response, leading to activation of an anti-tumour immune response.

Distribution	Two-compartment disposition model for the dose range of 1 - 20 mg/kg. Steady state is reached after 6-9 weeks of repeat dosing (2 to 3 cycles).	
Metabolism	Antibodies are primarily cleared by catabolism.	
Elimination	Half-life	27 days

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C - Indications and Status

- Non-small cell lung cancer (NSCLC)
- Small cell lung cancer (SCLC)
- Breast cancer
- Hepatocellular cancer

Refer to the product monograph for a full list and details of approved indications.

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D - Adverse Effects

Emetogenic Potential: Low

Extravasation Potential: None

Adverse reactions listed below are based on a phase III study in first-line NSCLC patients receiving atezolizumab monotherapy, mainly with incidences ≥10%. Severe adverse effects from other studies are also included.

Adverse effects marked with "†" are based on a pooled data set across multiple monotherapy studies.

ORGAN SITE	SIDE EFFECT* (%)	ONSET**
Cardiovascular	Arrhythmia (1%)	E
	Arterial thromboembolism (<1%)	E
	Hypotension (5%)	E
	Myocarditis (rare), pericarditis	E D
	Venous thromboembolism (4%)	E
Dermatological	Rash, pruritus , dry skin (15%) (may be severe)	E D
	Stevens-Johnson syndrome (rare)	E
	Toxic epidermal necrolysis (rare)	E
Gastrointestinal	Anorexia (15%)	E
	Constipation (12%)	E
	Diarrhea (11%) (may be severe; colitis - 1%)†	E D
	Nausea, vomiting (14%)	I E
General	Fatigue (26%)	E D

	Sarcoidosis (rare)	E
Hematological	Aplastic anemia (rare)	E
	Hemolytic anemia (autoimmune - rare)	E
	Myelosuppression (15%) (including anemia)	E
Hepatobiliary	Hepatitis (%) (immune-related) (rare)	E
	↑ LFTs (5%) (2% immune related hepatitis†)	E D
	Pancreatitis (rare)†	E D
Hypersensitivity	Hypersensitivity (1%)	I E
	Infusion related reaction (1%) †	I
Immune	Hemophagocytic lymphohistiocytosis (rare)	E
Infection	Infection (43%) (severe 11%)†	E
Metabolic / Endocrine	Abnormal electrolyte(s) (6%) (↓Na, Mg, K, Ca; ↑K, Ca)	E
	Adrenal insufficiency (rare)†	E D
	Hyperglycemia (4%) (including Type 1 Diabetes - rare†)	E D
	Hyperthyroidism (5%)	E D
	Hypophysitis (rare)†	E D
	Hypothyroidism (9%) (may be severe)	E D
Musculoskeletal	Musculoskeletal pain (15%)	E
	Rhabdomyolysis (rare)	E D
Nervous System	Encephalitis (Meningo-encephalitis) (rare)	E D
	Guillain-Barre syndrome (rare)†	E D
	Headache (9%)	E
	Myasthenia (rare - myasthenia gravis or myasthenic syndrome)†	E D
	Myelitis (rare)	E
	Myositis (rare)†	E D
	Peripheral neuropathy (7%)	E
Ophthalmic	Uveitis (and other ocular inflammatory toxicity) (rare)†	E D
Renal	Creatinine increased (1%)	E
	Nephritis (rare)†	D
Respiratory	Cough, dyspnea (14%)	E
	Pneumonitis (3%) †	E D
Vascular	Vasculitis (rare)	E

* "*Incidence*" may refer to an absolute value or the higher value from a reported range.
"*Rare*" may refer to events with < 1% incidence, reported in post-marketing, phase 1 studies, isolated data or anecdotal reports.

** I = *immediate* (onset in hours to days) E = *early* (days to weeks)
D = *delayed* (weeks to months) L = *late* (months to years)

The most common side effects for atezolizumab include infection, fatigue, anorexia, musculoskeletal pain, myelosuppression, rash/pruritus, cough/dyspnea, nausea/vomiting, constipation and diarrhea.

Refer to CCO's Immune Checkpoint Inhibitor Toxicity Management Guideline for detailed descriptions of Immune-related toxicities and their management.

Presentation of immune-mediated reactions may be different compared to other anti-cancer agents and early diagnosis and appropriate management is critical.

Immune-related reactions such as rash, pneumonitis, colitis, hepatitis, pancreatitis, nephritis, endocrinopathies, meningoencephalitis, and neuropathies were reported and may be severe or fatal. Onset may vary from days to many months.

Severe cutaneous adverse reactions (SCARS) (including reports of erythema multiforme, dermatitis bullous, toxic skin eruption, toxic epidermal necrolysis (TEN), exfoliative rash, and dermatitis exfoliative generalized) have occurred in patients who received atezolizumab as monotherapy or in combination with other anti-cancer agents.

Infections, including fatal cases, have been reported with atezolizumab. Pneumonia was the most common type of grade 3 or higher infection.

Severe **bleeding**, including fatal events, have been reported in NSCLC and HCC patients treated with the atezolizumab-bevacizumab combination.

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E - Dosing

Refer to protocol by which patient is being treated.

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

Avoid the use of corticosteroids or immunosuppressants before starting treatment.

Some treatment indications require a validated test to determine PD-L1 tumour status. Refer to the product monograph for details.

Pre-medications (prophylaxis for infusion reaction)

- There is insufficient evidence that routine prophylaxis with premedications reduce infusion reaction (IR) rates.
- Consider antipyretic and H1-receptor antagonist upon re-challenge.

Adults:

Atezolizumab IV and subcutaneous formulations are **not interchangeable**. The dosing and concentration of these products are different.

Monotherapy (NSCLC)

Intravenous:

- 840 mg Every 2 weeks
  or
- 1200 mg Every 3 weeks
  or
- 1680 mg Every 4 weeks

Combination therapy

Various dosing and schedules are used depending on the indication. Refer to the product monograph or related regimen monographs for details.

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	• Stop or slow the infusion rate. • Manage the symptoms. **Restart:** • No specific recommendations can be made at this time.	• Re-challenge with close monitoring. Consider pre-medication with antipyretic and H1-receptor antagonists.
3 or 4	• Stop treatment. • Aggressively manage symptoms.	• Permanently discontinue (do not re-challenge).

Dosage with 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

Dosage with 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 were observed between patients ≥ 65 years of age and younger patients. Data in patients > 75 years of age are too limited to draw conclusions.

Children:

The safety and efficacy in children and adolescents below 18 years of age have not been established.

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F - Administration Guidelines

Atezolizumab IV and subcutaneous formulations are **not interchangeable**. The dosing and concentration of these products are different.

- 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.
- For combination regimens, give atezolizumab prior to bevacizumab or chemotherapy if the drugs are given on the same day.
- 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.

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G - Special Precautions

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, cardiac, 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.

- Do not replace nab-paclitaxel with paclitaxel in combination with atezolizumab in unresectable locally advanced or metastatic triple negative breast cancer. An increase in the risk of death was reported in PD-L1 positive patients treated with atezolizumab and paclitaxel vs placebo and paclitaxel.

- Consider the bleeding risks of atezolizumab and bevacizumab combination in HCC and NSCLC before starting treatment. Patients with HCC should be evaluated for the presence of varices and have varices treated within 6 months before starting therapy with the atezolizumab-bevacizumab combination. The following patients were excluded from clinical trials: NSCLC patients who had clear tumour infiltration into the thoracic great vessels or clear cavitation of pulmonary lesion (as seen on imaging), or HCC patients with bleeding varices (including recent bleeds), untreated varices or varices at high risk of bleeding.

- Severe infections have been observed in clinical trials.

Other Drug Properties:

- Carcinogenicity: Unknown

Pregnancy and Lactation:

- Genotoxicity: Unknown
- Fetotoxicity: Documented in animals
- Pregnancy:
  Atezolizumab is not recommended for use in pregnancy. Adequate contraception should be used by both patients and their partners during treatment, and for at least **5 months** after the last dose.

- Breastfeeding:
  Breastfeeding is not recommended during treatment and for at least **5 months** after the last dose.

- Fertility effects: Probable
  Documented in studies, in female animals

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H - Interactions

- 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. Corticosteroids may be used as premedication (e.g. antiemetic) when given with chemotherapy.
- Acetaminophen may affect the response to immune checkpoint inhibitors. Further clinical studies are needed to determine the exact mechanism and the appropriate clinical management (Bessede et al, 2022).

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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

Monitor Type	Monitor Frequency
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 - Supplementary Public Funding

New Drug Funding Program (NDFP Website)

- Atezolizumab - Advanced or Metastatic Non-Small Cell Lung Cancer
- Atezolizumab with Bevacizumab (Biosimilar) - Previously Untreated Unresectable or Metastatic Hepatocellular Carcinoma
- Atezolizumab - In Combination with Etoposide and Platinum for Extensive-Stage Small Cell Lung Cancer
- Atezolizumab - Adjuvant Treatment for Non-Small Cell Lung Cancer

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K - References

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May 2025 Updated Adverse effects section

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L - Disclaimer

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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