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Reimbursement Recommendation

Atezolizumab (Tecentriq IV and Tecentriq SC)

Indication: As monotherapy for the first-line treatment of patients with metastatic NSCLC whose tumours have high PD-L1 expression (PD-L1 stained ≥ 50% of TCs or PD-L1 stained tumour-infiltrating immune cells [ICs] covering ≥ 10% of the tumour area), as determined by a validated test and who do not have EGFR or ALK genomic tumour aberrations

Sponsor: Hoffmann-La Roche Limited

Final recommendation: Reimburse with conditions

Summary

What Is the Reimbursement Recommendation for Tecentriq?

Canada's Drug Agency (CDA-AMC) recommends that Tecentriq IV and Tecentriq SC be reimbursed by public drug plans for the first-line treatment of patients with metastatic non–small cell lung cancer (NSCLC) whose tumours have high PD-L1 expression, as determined by a validated test, and who do not have *EGFR* or *ALK* genomic tumour aberrations if certain conditions are met.

Why Did CDA-AMC Recommend Reimbursement?

A subcommittee of the pan-Canadian Oncology Drug Review Expert Review Committee (pERC) determined that Tecentriq IV and SC demonstrate acceptable clinical value versus immunotherapies (i.e., pembrolizumab and cemiplimab) in patients with metastatic NSCLC. This determination was enough for pERC to recommend that Tecentriq IV and SC be reimbursed. Given that Tecentriq is expected to be an alternative to pembrolizumab and cemiplimab, *acceptable clinical value* refers to at least comparable value versus the PD-1 inhibitors.

Evidence from a clinical trial (IMpower110) showed that treatment with Tecentriq delays cancer progression and extends life compared with chemotherapy alone in patients with NSCLC that has spread to other parts of the body.

Patients identified a need for additional treatment options that are life extending and improve their quality of life. Tecentriq was considered an alternative immunotherapy option, with both IV and subcutaneous (SC) routes of administration that may offer an unmet clinical benefit for some patients.

Which Patients Are Eligible for Coverage?

Tecentriq should only be covered according to the criteria used by the public drug plans for other PD-1 inhibitors for the first-line treatment of patients with metastatic NSCLC whose tumours have high PD-L1 expression.

What Are the Conditions for Reimbursement?

In addition to the pre-existing criteria for other PD-1 inhibitors, Tecentriq should only be reimbursed if it is not used in combination with another anticancer therapy, if it is prescribed by a clinician with expertise in managing lung cancer, and if the cost of Tecentriq does not exceed

Summary

the drug program cost of treatment with the least costly PD-1 inhibitor monotherapy for the same indication.

Review Background

- **Disease background:** Lung cancer is among the most commonly diagnosed cancers and is the leading cause of death from cancer in Canada. The Canadian Cancer Society estimated that there would be 32,100 new lung and bronchus cancer diagnoses in Canada in 2024. NSCLC is the most common type of lung cancer, accounting for about 88% of all cases.
- **Indication and reimbursement request:** Atezolizumab (Tecentriq) has been approved by Health Canada for use as monotherapy for the first-line treatment of patients with metastatic NSCLC whose tumours have high PD-L1 expression (PD-L1 stained ≥ 50% of tumour cells or PD-L1 stained tumour-infiltrating immune cells covering ≥ 10% of the tumour area), as determined by a validated test, and who do not have *EGFR* or *ALK* genomic tumour aberrations. The sponsor is seeking reimbursement in accordance with the existing reimbursement criteria for the most appropriate comparators (i.e., pembrolizumab and cemiplimab).
- **Drug under review:** Atezolizumab is a PD-L1 inhibitor. It is available for both SC injection and IV infusion. The dosages recommended in the product monograph are 1,875 mg every 3 weeks for SC injection and 840 mg every 2 weeks, 1,200 mg every 3 weeks, or 1,680 mg every 4 weeks for IV infusion.
- **Treatment costs:** At the submitted price of $4,743 per 840 mg vial or $6,776 per 1,200 mg vial, the 28-day cost of IV atezolizumab is expected to be $9,035 to $9,486 per patient depending on the dosage regimen. At the submitted price of $6,453 per 1,875 mg vial, the 28-day cost of SC atezolizumab is expected to be $8,604 per patient.
- **Tailored review process:** This application was reviewed through the tailored review process. When submitting an application for a tailored review, the sponsor does not claim added clinical benefit with the drug under review compared with the most appropriate comparators and the sponsor requests alignment with the existing reimbursement criteria for the most appropriate comparators. A subcommittee of the relevant expert committee deliberates on and, when there is unanimous agreement, issues the recommendation for a tailored review application. The focus of the subcommittee deliberations is whether the evidence supports that the drug under review demonstrates comparable clinical benefit and harms to 1 or more appropriate comparators, and whether the evidence supports the drug being reimbursed in accordance with the existing reimbursement criteria for the most appropriate comparators.

Highlights of Input From Interested Parties

The patient groups (Lung Cancer Canada, the Lung Health Foundation, and the Canadian Cancer Survivor Network) noted the following regarding impacts of the disease, unmet needs, and important outcomes:

- Patient groups described the diagnosis of metastatic lung cancer as a devastating and frightening experience for patients and their caregivers, and described a variety of troubling emotional and physical symptoms.

- Commonly reported physical symptoms included fatigue, shortness of breath, coughing, changes in body weight, and pain. Patients reported negative and challenging impacts on their emotional well-being and family relationships. Feelings of isolation were common, as was the belief that too much time is spent at medical appointments.
- Patients are seeking treatments that will extend survival, slow disease progression, improve symptoms, and help patients improve their quality of life. Additional treatment options are valued as they may provide another option if alternative treatments are not effective or cannot be tolerated by the patient.

The clinician groups (the Lung Cancer Canada Medical Advisory Committee and the Ontario Health [Cancer Care Ontario] Lung Cancer Drug Advisory Committee) and the clinical experts consulted by CDA-AMC noted the following regarding unmet needs arising from the disease and place in therapy for the drug under review:

- The availability of a PD-1 or PD-L1 inhibitor that can be administered subcutaneously is a key unmet need identified by patients and clinicians that could be addressed by reimbursement of atezolizumab for those living with metastatic NSCLC who are eligible for treatment in the first-line setting.

The participating public drug programs raised potential implementation issues related to considerations for initiation, renewal, and discontinuation; generalizability of trial populations to broader populations; and system and economic issues.

Recommendation

The pERC subcommittee recommends that atezolizumab IV and SC be reimbursed as monotherapy for the first-line treatment of patients with metastatic NSCLC whose tumours have high PD-L1 expression, as determined by a validated test, and who do not have *EGFR* or *ALK* genomic tumour aberrations, only if the conditions listed in Table 1 are met.

Table 1: Reimbursement Conditions and Reasons

Reimbursement condition	Reason	Implementation guidance
Initiation		
1. Eligibility for atezolizumab (IV or SC) should be based on the criteria used by each of the public drug plans for reimbursement of PD-1 inhibitors as monotherapy for the first-line treatment of patients with metastatic NSCLC whose tumours have high PD-L1 expression.	There is insufficient evidence that atezolizumab is clinically superior or inferior to pembrolizumab or cemiplimab for the first-line treatment of patients with metastatic NSCLC whose tumours have high PD-L1 expression.	**Existing criteria:** The initiation criteria for pembrolizumab and cemiplimab may vary across participating drug programs, but are summarized as 1 of the following: • PD-L1 stained ≥ 50% of tumour cells • no prior treatment in the relevant line of therapy (i.e., metastatic disease) • no *EGFR*, *ALK,* or *ROS1* mutations • no uncontrolled or symptomatic CNS metastases • good performance status. **Locally advanced disease:** The scope of the

Reimbursement condition	Reason	Implementation guidance
		CDA-AMC review was limited to the indication that has been approved by Health Canada and does not include patients with stage III disease or locally advanced disease; however, the pERC subcommittee and the clinical experts noted it could be appropriate for jurisdictions to reimburse atezolizumab for the same patient populations the PD-1 inhibitors are currently reimbursed for (i.e., pembrolizumab and cemiplimab). **Prior PD-1 or PD-L1 inhibitor:** Consistent with the reimbursement criteria for pembrolizumab and cemiplimab, patients who received prior treatment with an anti–PD-1 or anti–PD-L1 therapy in the nonmetastatic setting (e.g., neoadjuvant or adjuvant setting) should be eligible for atezolizumab in the first-line metastatic setting if progression to metastatic disease occurred at least 6 months after the completion of the prior anti–PD-1 or anti–PD-L1 therapy in the advanced disease setting.
Discontinuation		
2. Discontinuation of reimbursement for atezolizumab should be based on the criteria used by each of the public drug plans for the reimbursement of PD-1 inhibitors as monotherapy for the first-line treatment of patients with metastatic NSCLC whose tumours have high PD-L1 expression.	The existing discontinuation criteria for pembrolizumab and cemiplimab are appropriate for atezolizumab.	**Existing criteria:** The discontinuation criteria for pembrolizumab and cemiplimab may vary across participating drug programs, but are summarized as 1 of the following: • disease progression • unacceptable toxicity. **Interruption due to toxicity:** Patients who previously discontinued atezolizumab due to toxicity and for whom the toxicity has subsequently resolved should be eligible for reimbursement until the discontinuation criteria are met. **Relapse after complete response:** Patient who experiences a relapse after discontinuing atezolizumab due to a confirmed complete response should be eligible for reimbursement until the discontinuation criteria are met. **Duration of treatment:** The product monograph for atezolizumab does not specify a maximum number of doses and the IMpower110 trial did not stop administration after a maximum number of cycles. As such, there is no evidence to inform a reimbursement condition that would limit administration of atezolizumab to a maximum number of cycles. However, pERC agreed with the clinical experts consulted by CDA-AMC

Reimbursement condition	Reason	Implementation guidance
		that alignment of treatment duration with other currently reimbursed treatment options (i.e., pembrolizumab and cemiplimab, which have a maximum treatment duration of 2 years and re-treatment up to an additional 1 year if certain conditions are met) in this setting would be appropriate. **Disease progression:** Reimbursement for pembrolizumab and cemiplimab is discontinued at the time of disease progression. Although the product monograph for atezolizumab states that treatment may continue until loss of clinical benefit, the subcommittee concluded that reimbursement of atezolizumab should be discontinued at the time of disease progression. This will ensure alignment of the reimbursement criteria for atezolizumab, pembrolizumab, and cemiplimab.
Prescribing		
3. Atezolizumab should be prescribed by clinicians with expertise in managing lung cancer.	This is meant to ensure that atezolizumab is prescribed for appropriate patients and that adverse effects are managed in an optimized and timely manner.	—
4. Reimbursement should be provided for atezolizumab monotherapy and not when used in combination with other anticancer therapies.	This condition aligns with the indication under review.	—
Pricing		
5. The drug program cost of atezolizumab should be negotiated so it does not exceed the drug program cost of treatment with the least costly PD-1 inhibitor monotherapy for the same indication.	Based on the subcommittee's assessment of the evidence, atezolizumab is expected to have comparable clinical benefits and harms to relevant comparators. Therefore, atezolizumab should be priced such that the total treatment cost for atezolizumab is no more than that of the least costly PD-1 inhibitor.	The duration of treatment with atezolizumab may be longer than other PD-1 inhibitors if a maximum number of cycles is not applied. Even if the price of atezolizumab is negotiated to not exceed the drug program cost of treatment with the least costly of pembrolizumab or cemiplimab, expenditure on atezolizumab may increase the overall budgetary amount spent by the drug plans. Additional price reductions beyond that recommended in the pricing condition may be necessary to avoid increasing the overall budget.

CDA-AMC = Canada's Drug Agency; CNS = central nervous system; NSCLC = non–small cell lung cancer; pERC = pan-Canadian Oncology Drug Review Expert Review Committee; SC = subcutaneous.

Rationale for the Recommendation

Clinical Value

The pERC subcommittee deliberated on whether the evidence supports that atezolizumab demonstrates comparable clinical benefit and harms to 1 or more appropriate comparators for first-line treatment of patients with metastatic NSCLC whose tumours have high PD-L1 expression, as determined by a validated test, and who do not have *EGFR* or *ALK* genomic tumour aberrations. Based on the totality of the clinical evidence, the subcommittee concluded that atezolizumab demonstrates comparable clinical benefit and harms to pembrolizumab and cemiplimab and therefore has acceptable clinical value.

Evidence from a pivotal phase III clinical trial (IMpower110) demonstrated that atezolizumab results in clinically meaningful improvements compared with platinum-based chemotherapy in outcomes that are relevant for the management of NSCLC in the first-line metastatic setting, including overall survival (OS), progression-free survival (PFS), and objective response. The estimates of effect from the sponsor's network meta-analysis (NMA) were limited by imprecision (i.e., wide credible intervals [CrIs]), making it challenging to evaluate if there are meaningful differences across the different PD-1 and PD-L1 inhibitors (i.e., atezolizumab, pembrolizumab, and cemiplimab) approved for use in the target population. The subcommittee concluded that atezolizumab is likely associated with similar clinical benefits to pembrolizumab and cemiplimab (i.e., consistent with the sponsor's claim of no added clinical benefit) based on the effect sizes reported in the IMpower110 trial, the input from clinical specialists, and the similar mechanism of action compared with PD-1 inhibitors.

The sponsor's application is seeking reimbursement for both the IV and SC formulations of atezolizumab. There was no data for the SC formulation submitted for the target patient population, as the SC formulation was evaluated in a different clinical development program. The SC formulation was approved by Health Canada in March 2024, and the subcommittee accepted the extrapolation of the indications approved for the IV formulation to the SC formulation.

Patients and clinicians noted that reimbursement of atezolizumab would be beneficial as it would provide an SC treatment option for this patient population.

Further information on the subcommittee's discussion around clinical value is provided in the Summary of Deliberation section.

Developing the Recommendation

The determination of acceptable clinical value was sufficient for the pERC subcommittee to recommend reimbursement of atezolizumab.

Because the pERC subcommittee recommended that atezolizumab be reimbursed, it also deliberated on whether reimbursement conditions should be added to address important economic considerations, health system impacts, or social and ethical considerations, or to ensure clinical value is realized. The resulting reimbursement conditions, with accompanying reasons and implementation guidance, are stated in Table 1.

Summary of Deliberation

The subcommittee considered all domains of value of the deliberative framework before developing its recommendation: clinical value, unmet clinical need, distinct social and ethical considerations, economic considerations, and impacts on health systems. For further information on the domains of value, refer to Expert Committee Deliberation at Canada's Drug Agency.

The subcommittee considered the following key discussion points, organized by the 5 domains of value.

Clinical Value

- **Appropriate comparators:** Pembrolizumab and cemiplimab were considered the appropriate comparators for atezolizumab.
- **Efficacy versus platinum-based chemotherapy:** One randomized controlled phase III trial (IMpower110) demonstrated that atezolizumab results in clinically meaningful improvements compared with chemotherapy in outcomes that are relevant for the management of NSCLC in the first-line metastatic setting, including OS, PFS, and objective response. The overall trial population of the IMpower110 trial was broader than the approved indication; therefore, the sponsor submitted subgroup data for patients with high PD-L1 expression (i.e., PD-L1 stained at least 50% of tumour cells or PD-L1 stained tumour-infiltrating immune cells covering at least 10% of the tumour area) (n = 107 for atezolizumab and n = 98 for chemotherapy). The subcommittee considered that the treatment effects for OS and PFS compared with platinum-based chemotherapy were clinically meaningful and aligned with the expectations for a PD-1 or PD-L1 inhibitor.
- **Efficacy versus pembrolizumab and cemiplimab:** The sponsor submitted an NMA of atezolizumab versus pembrolizumab, cemiplimab, and platinum-based chemotherapy. The estimates of effect from the NMA were limited by imprecision (i.e., wide CrIs), making it challenging to evaluate if there are meaningful differences across the different PD-1 and PD-L1 inhibitors approved for use in the target population (i.e., atezolizumab, pembrolizumab, and cemiplimab). Although the evidence submitted by the sponsor does not support any definitive conclusions about the efficacy or safety of atezolizumab relative to pembrolizumab or cemiplimab, the clinical experts suggested that atezolizumab may present an additional treatment option for patients with metastatic NSCLC with high PD-L1 expression, particularly given the availability of a SC formulation.
- **Adverse events (AEs):** Indirect comparisons submitted by the sponsor included AEs and discontinuations due to AEs. The indirect estimates of effect were associated with very wide CrIs and lacked the precision to evaluate if there are meaningful differences across the treatments. The clinical experts consulted by CDA-AMC noted that clinical trial data from the IMpower110 trial do not suggest an increase or decrease in AEs compared with the alternative treatments and the overall AE profile of atezolizumab is similar to pembrolizumab and cemiplimab.
- **Dosing considerations:** The dosing recommendations in the product monographs for atezolizumab, pembrolizumab, and cemiplimab all state that treatment should be discontinued in the event of

unmanageable toxicity, but differ with respect to treatment after disease progression and the duration of therapy (i.e., maximum number of treatment cycles):

- **Disease progression:** The product monographs for pembrolizumab and cemiplimab state that treatment should be discontinued at the time of disease progression, whereas the product monograph for atezolizumab states that treatment can continue "until loss of clinical benefit." This is consistent with the discontinuation criteria used in the IMpower110 trial, in which loss of clinical benefit was defined as the absence of symptoms and signs (including worsening of laboratory values) indicating unequivocal progression of disease; no decline in Eastern Cooperative Oncology Group (ECOG) performance status; absence of tumour progression at critical anatomic sites that cannot be readily managed and stabilized by protocol-allowed medical interventions before repeat dosing; or evidence of clinical benefit as assessed by the investigator. The subcommittee concluded that reimbursement of atezolizumab should be discontinued at the time of disease progression, noting that clinicians and the public drug programs indicated a preference for alignment of the reimbursement criteria for PD-1 and PD-L1 inhibitors and the sponsor requested alignment in their application to CDA-AMC.
- **Duration of therapy:** The product monograph for pembrolizumab specifies a maximum number of cycles for those without disease progression (up to 24 months or 35 doses for 200 mg or 18 doses for 400 mg, whichever is longer). This is reflected in the CDA-AMC recommendation for pembrolizumab for the same indication (and others that have been issued for pembrolizumab). The product monograph for cemiplimab does not recommend a maximum number of cycles, but the recommendation from CDA-AMC specified a maximum of 108 weeks based on the upper limit of cycles administered in the EMPOWER-LUNG 1 trial. In contrast, the product monograph for atezolizumab does not specify a maximum number of doses and the IMpower110 clinical trial did not stop administration after a maximum number of cycles. The subcommittee concluded that the potential for a longer duration of treatment with atezolizumab should not result in incremental budget impact for the drug programs because, in their application to CDA-AMC, the sponsor assumed that the duration of therapy with atezolizumab would be the same as pembrolizumab and cemiplimab and there is no evidence to suggest that atezolizumab is superior to the alternative treatments. Clinical experts consulted by CDA-AMC noted that capping the duration of therapy with atezolizumab in a manner similar to pembrolizumab and cemiplimab could be appropriate (i.e., a maximum duration of 2 years).

- **Clinical value:** Based on all the preceding considerations, the subcommittee determined that atezolizumab demonstrates comparable clinical benefit and harms to pembrolizumab and cemiplimab.

Unmet Clinical Need

- **Input on unmet clinical need:** Patients and clinicians identified a need for additional treatment options that will extend survival, slow disease progression, improve symptoms, and help patients

improve their quality of life. Additional treatment options are valued as they may provide another option if alternative treatments are not effective or cannot be tolerated by the patient.

- **Deliberation on significant unmet clinical need:** The subcommittee reviewed the considerations for unmet clinical need. Given that deliberations for tailored reviews have a specific focus, further deliberation on whether there was significant unmet clinical need was not required.

Distinct Social and Ethical Considerations

- **Availability of an SC treatment option:** Patients and clinicians noted that reimbursement of atezolizumab would be beneficial as it would provide an SC option for the first-line treatment of patients with metastatic NSCLC whose tumours have high PD-L1 expression. It was noted that SC atezolizumab has completed pan-Canadian Pharmaceutical Alliance negotiations for other indications.

Economic Considerations

- **Cost of atezolizumab versus relevant comparators:** Based on the submitted prices for atezolizumab IV ($4,743 per 840 mg vial or $6,776 per 1,200 mg vial) and SC ($6,453 per 1,875 mg vial), and publicly available list prices for its comparators, reimbursement of atezolizumab is expected to be associated with lower drug costs to the health care system versus cemiplimab and fixed-dose pembrolizumab (incremental savings: $1,447 to $3,129 per 28-day cycle), and higher or lower cost versus weight-based pembrolizumab, depending on the dosage of atezolizumab (range, incremental savings: $313 to incremental cost: $569 per 28-day cycle).

Impacts on Health Systems

- **Anticipated budget impact:** CDA-AMC estimates that over the next 3 years, 482 of the 5,339 eligible patients will receive atezolizumab and that reimbursement of atezolizumab for the Health Canada–indicated population may be cost saving for the public drug plans (savings: $3.5 million over 3 years; expenditure on atezolizumab: $24 million over 3 years). The subcommittee discussed that whether savings are realized by the drug plans will depend on the proportion of patients who receive the IV versus SC formulation of atezolizumab, duration of treatment, and confidentially negotiated prices for comparators.
- **Organizational implications:** The subcommittee noted that the SC administration of atezolizumab could have a reduced impact on health system resources compared with IV administration of the comparators (i.e., reduced chair time); however, the extent of cost savings is uncertain.

Sources of Information Used by the Subcommittee

To make its recommendation, the subcommittee considered the following information (links to the full documents for the review can be found on the project webpage).

- the CDA-AMC review of the clinical and pharmacoeconomic evidence submitted by the sponsor related to atezolizumab (refer the Main Report and Supplemental Material document)
- the sponsor's comments on the draft report and the CDA-AMC responses
- patients' perspectives gathered by 3 patient groups, Lung Cancer Canada, the Lung Health Foundation, and the Canadian Cancer Survivor Network (refer to the Patient and Clinician Group Input document)
- input from 2 clinician groups, the Lung Cancer Canada Medical Advisory Committee and the Ontario Health (Cancer Care Ontario) Lung Cancer Drug Advisory Committee (refer to the Patient and Clinician Group Input document)
- input from public drug programs that participate in the reimbursement review process (refer to the Supplemental Material document)
- input from 2 clinical experts with expertise in the management of lung cancer who were consulted by CDA-AMC.

pERC Information

Members of the Committee

Dr. Catherine Moltzan (Chair), Dr. Kelvin Chan (Vice-Chair), Paul Agbulu, Dr. Phillip Blanchette, Dr. Matthew Cheung, Dr. Michael Crump, Annette Cyr, Dr. Jennifer Fishman, Dr. Jason Hart, Terry Hawrysh, Dr. Yoo-Joung Ko, Dr. Aly-Khan Lalani, Amy Peasgood, Dr. Anca Prica, Dr. Michael Raphael, Dr. Adam Raymakers, Dr. Patricia Tang, Dr. Pierre Villeneuve, and Danica Wasney

A subcommittee composed of 4 pERC members was convened. None had a conflict of interest that precluded their participation.

Meeting date: November 17, 2025

Conflicts of interest: None

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