Ontario Health | Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Atezolizumab - Adjuvant Treatment for Non-Small Cell Lung Cancer

(This form must be completed before the first dose is dispensed.)

1. Patient Profile

* Surname: .....

* Given Name: .....

* OHIN: ..... * Chart Number: .....

* Postal Code: .....

* Height (cm): ..... * Weight (kg): ..... * BSA (m^2): .....

* Gender: ○ Male ○ Female ○ Other

* Date of Birth: ....
Day Month Year

* Site:

* Attending Physician (MRP- Most Responsible Physician): .....

Requested Prior Approval ☐ Yes * Patient on Clinical Trial ○ Yes ○ No

Other (specify): .....

Specify Arm:
○ Standard of care arm ○ Experimental arm
○ Blinded / Unknown

Prior Approval Request

* Select the appropriate prior approval scenario:

○ 1-Unknown primary (submit pathology report and clinic note)
○ 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
○ 3-Regimen modification - schedule (complete questions a and b)
○ 4-Regimen modification - drug substitutions (complete questions a and c)
○ 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)
○ 6-Maintenance therapy delay (submit clinic note)
○ 7-Prior systemic therapy clinical trials (complete question g)
○ 8-Modification due to supply interruption/drug shortage
○ 9-Supplemental doses requested
○ Other (specify)

All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.

a. Co-morbidities / toxicity / justification:

b. Intended regimen schedule:

c. Intended regimen:

d. Drug(s) to be held:

e. Rationale for holding drug(s):

f. Intention to introduce drug at a later date? ☐ Yes

g. Prior clinical trial identifier (e.g., NCT ID, trial name) and treatment description (e.g., arm, drug/regimen):

h. Anticipated date of first treatment: Day Month Year

i. Additional comments:

2. Eligibility Criteria

Atezolizumab monotherapy is used for the adjuvant treatment of adult patients with resected stage II or III non-small cell lung cancer (NSCLC) (excluding T2bN0)* whose tumours have PD-L1 expression on 50% or more of tumour cells and do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations. ☐ Yes

Treatment is only for patients who have completely resected NSCLC, no disease progression after platinum-based adjuvant chemotherapy, and who have a good performance status.

Treatment with atezolizumab should be initiated within 3 to 8 weeks from the completion of chemotherapy.

*Based on the American Joint Committee on Cancer TNM staging system, 8th edition.

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Is the patient transitioning from a private payer or compassionate program? ○ Yes ○ No

c. If yes, please indicate the funding source. ○ Private payer ○ Manufacturer patient support program

d. If yes, please indicate the date of the last administered dose. ..... Day ..... Month ..... Year

e. If yes, how many doses of atezolizumab given every 2 weeks did the patient receive prior to the transition?
○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6
○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13
○ 14 ○ 15 ○ 16 ○ 17 ○ 18 ○ 19 ○ 20
○ 21 ○ 22 ○ 23

f. If yes, how many doses of atezolizumab given every 3 weeks did the patient receive prior to the transition?
○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6
○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13
○ 14 ○ 15

g. If yes, how many doses of atezolizumab given every 4 weeks did the patient receive prior to the transition?
○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6
○ 7 ○ 8 ○ 9 ○ 10 ○ 11

h. Tumour histologic type ○ Squamous ○ Non-squamous

4. Funded Dose

Atezolizumab 840 mg as an intravenous (IV) infusion every 2 weeks, 1200 mg as an IV infusion or 1875 mg subcutaneously (SC) every 3 weeks, or 1680 mg as an IV infusion every 4 weeks.

Treatment should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 48 weeks (i.e., 12 cycles every 4 weeks, 16 cycles every 3 weeks, or 24 cycles every 2 weeks), whichever comes first.

[ST-QBP regimen code: ATEZ]

Please select the approved atezolizumab dosing schedule:

- ○ 840 mg as an intravenous (IV) infusion every 2 weeks
- ○ 1200 mg as IV infusion or 1875 mg SC every 3 weeks
- ○ 1680 mg as an IV infusion every 4 weeks

5. Notes

1. Patients who are not eligible for surgical resection and initiation of platinum-based adjuvant chemotherapy are ineligible for atezolizumab funding.

2. Patients treated with an immune checkpoint inhibitor in the curative setting who have a disease-free interval of 6 months or greater from the last dose may be eligible for one line of PD-1 or PD-L1 inhibitor therapy for advanced NSCLC provided all other eligibility criteria are met.

3. The IV and SC formulations of atezolizumab are not interchangeable.

6. FAQs

1. **My patient is currently receiving atezolizumab through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding for atezolizumab through the New Drug Funding Program (NDFP)?**

   Provided the eligibility criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage of atezolizumab through the NDFP.

   Patients who meet the eligibility criteria may be transitioned to NDFP funding through a regular eClaims enrolment. If there is clinical uncertainty regarding eligibility, these requests may be submitted as a prior approval including a clinic note from the time of initiation as well as the most recent clinic note outlining the response to treatment (if able to assess).

   Funding is for up to a maximum of 48 weeks, regardless of funding source.

2. **My patient with stage II to III NSCLC underwent a complete resection and platinum-based adjuvant chemotherapy but more than 8 weeks have elapsed since its completion. Now that adjuvant atezolizumab is publicly funded, is it an option for my patient?**

   On a time-limited basis only, atezolizumab may be considered for patients within 12 weeks from the completion of platinum-based chemotherapy. Please submit as a prior approval request in eClaims including the most recent clinic note outlining the treatment history including the date platinum-based adjuvant chemotherapy was completed.

3. **My patient was started on a platinum-based doublet as adjuvant chemotherapy but was unable to complete treatment due to toxicities. Will they be eligible for adjuvant atezolizumab?**

   Provided that all other eligibility criteria are met, patients who subsequently become platinum ineligible due to toxicities will be eligible for adjuvant atezolizumab.

4. **My patient is currently receiving atezolizumab IV. Can my patient be switched over to the SC formulation for the remainder of their treatment cycles?**

   At the discretion of the treating physician, patients currently on atezolizumab IV may be switched over to the SC formulation for the remainder of the funded doses according to the specific policy. Sites are not required to re-enroll in the updated enrolment form to submit treatment claims for atezolizumab SC.

7. Supporting Documents

- None required at time of enrolment.

  In the event of an audit or upon request, the following should be available to document eligibility:

  - Surgical pathology report(s) and/or clinic note(s) documenting complete surgical resection, tumour staging and use of platinum-based adjuvant chemotherapy.
  - Biomarker report showing no EGFR or ALK driver mutations and a tumour proportion score specifying PD-L1 expression on 50% or more of tumour cells.

Signature of Attending Physician (MRP-Most Responsible Physician): .....

....
Day Month Year

Form 1089