Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - Previously Untreated High-Risk Early-Stage Triple Negative Breast 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
○ 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

Pembrolizumab is used for the treatment of adult patients with high-risk early-stage triple negative breast cancer (TNBC*) in combination with chemotherapy as neoadjuvant therapy, and then continued as monotherapy in the adjuvant setting.

☐ Yes

Treatment is only for patients with good performance status who have not received prior systemic therapy for non-metastatic TNBC and with no clinical contraindication to immunotherapy.

Eligible non-metastatic patients include those with T1c, N1-2 or T2-4, N0-2 as per the American Joint Committee on Cancer (AJCC). Staging is based on radiological and/or clinical assessment.

*Refers to lack of expression of the estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) as per the American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines.

3. Baseline Information

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

b. AJCC staging based on radiological and/or clinical assessment:
○ T1c, N1-2 ○ T2, N0-2 ○ T3, N0-2 ○ T4, N0-2

c. Select the chemotherapy regimen to be used in the neoadjuvant setting:
○ Doxorubicin, cyclophosphamide, carboplatin, and paclitaxel
○ Doxorubicin, cyclophosphamide, and paclitaxel
○ Fluorouracil, epirubicin, cyclophosphamide, and docetaxel
○ Docetaxel, cyclophosphamide (if anthracycline contraindication)

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

e. If yes to 3d, how many doses of pembrolizumab 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 ○ 16

f. If yes to 3d, how many doses of pembrolizumab given every 6 weeks did the patient receive prior to the transition?
○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5
○ 6 ○ 7 ○ 8

4. Funded Dose

Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days, or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days.

Pembrolizumab is given in combination with neoadjuvant chemotherapy then as a single agent in the adjuvant setting.

Treatment should be continued until confirmed disease progression or recurrence or unacceptable toxicity up to a maximum of 1 year (i.e., 17 doses given every 3 weeks, or 9 doses given every 6 weeks), whichever occurs first.

[ST-QBP regimen codes: AC+PEMB, AC(DD)+PEMB, CRBPPACL(W)+PEMB, PACL+PEMB, PACL(W)+PEMB, PACL(DD)+PEMB, FEC+PEMB, DOCE+PEMB, CYCLDOCE+PEMB followed by PEMB for the monotherapy phase]

5. Notes

1. Patients with T1a/T1bN0 (determined by radiographic and/or clinical assessment) disease are not eligible.

2. Functional TNBC is defined as hormone receptor (HR)-low disease (estrogen receptor and/or progesterone receptor 1-10% staining by IHC). According to the Canadian Agency for Drugs and Technologies in Health's provisional funding algorithm, patients with HR-low disease may be treated as functionally triple-negative and should consistently pursue treatments based on the same funding algorithm (i.e., TNBC), unless new information becomes available (e.g., new biopsy with updated biomarker results).

6. FAQs

i. **My patient is currently receiving pembrolizumab through non-publicly funded means. Can my patient be transitioned over to receive funding 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 pembrolizumab funding through NDFP. Please submit as a prior approval request including a clinic note from initiation of neoadjuvant treatment as well as the most recent clinic note discussing treatment response (if able to assess).

Of note, patients enrolled in the manufacturer's Patient Support Program (PSP) will continue to receive treatment through the PSP until April 6, 2023, inclusive. While these patients may enroll before April 7, 2023, please be aware any treatments submitted to eClaims that were given on or before April 6, 2023, will be denied.

Based on the recommendations from Canadian Agency for Drugs and Technologies in Health (CADTH), Ontario Health (Cancer Care Ontario) does not reimburse hospitals for pembrolizumab given as a fixed or flat dose (i.e., 200 mg IV every 3 weeks or 400 mg IV every 6 weeks) under this policy. Regardless of the patient's prior funding source or prior dosing, the NDFP funded dose is pembrolizumab 2 mg/kg IV given every 3 weeks, up to a maximum of 200 mg per dose or 4 mg/kg given every 6 weeks, up to a maximum of 400 mg per dose. NDFP will fund a total duration of 17 doses given every 3 weeks or 9 doses given every 6 weeks, regardless of funding source.

ii. **A variety of chemotherapy options are available as neoadjuvant therapy in early-stage TNBC. Which neoadjuvant regimens can be used in combination with pembrolizumab?**

Any taxane and anthracycline based regimens may be used in combination with pembrolizumab for the neoadjuvant portion. For patients with a contraindication to anthracyclines, a taxane-based regimen could be considered.

iii. **My patient is currently receiving neoadjuvant chemotherapy for early-stage TNBC. Can pembrolizumab be added?**

Provided the eligibility criteria were met at the time of neoadjuvant treatment initiation and the patient's disease has not progressed, your patient may be eligible for the addition of pembrolizumab. Please submit a prior approval request in eClaims, including a clinic note from the initiation of therapy and a recent clinic note discussing treatment response (if able to assess).

iv. **My patient has completed neoadjuvant chemotherapy. Will single agent pembrolizumab be funded by NDFP if it is prescribed in the adjuvant setting?**

Patients who have completed neoadjuvant therapy would not be eligible for pembrolizumab funding in the adjuvant setting.

v. **My patient's surgery was delayed. Will single agent pembrolizumab be funded by NDFP until surgery occurs?**

If surgery has been delayed, pembrolizumab given as a single agent will be eligible for funding until surgery occurs. NDFP will provide funding for a total of one year (i.e., 17 doses given every 3 weeks, or 9 doses given every 6 weeks) which includes the combination of doses administered in the neoadjuvant and adjuvant settings.

vi. **My patient experienced treatment delays in pembrolizumab administration (e.g., post-operative recovery, held during radiation). Do all doses of pembrolizumab have to be administered within 12 months of initiation of therapy?**

NDFP will provide funding for a total of 17 doses of pembrolizumab if given every 3 weeks or 9 doses if given every 6 weeks, outside of the twelve sequential calendar months if the patient requires a delay in treatment.

7. Supporting Documents

None required at time of enrolment.

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

- Pathology report(s) confirming tumor markers, risk category, and stage of disease.
- Clinic note(s) confirming treatment history and/or clinical assessment.

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

20	02	2024
Day	Month	Year