Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - Locally Recurrent Unresectable or Metastatic 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 in combination with chemotherapy for the treatment of adult patients with locally recurrent unresectable or metastatic triple negative breast cancer (TNBC).* ☐ Yes

Patients must have:

- Tumour(s) expressing PD-L1 with a combined positive score (CPS) of ≥ 10 (as determined by a validated test); AND
- A good performance status; AND
- If applicable, a minimum 6-month interval from completion of treatment with curative intent to recurrence of local or distant disease.

Patients must not have:

- Received prior chemotherapy for metastatic or incurable locally advanced disease; OR
- Contraindications to immunotherapy; OR
- Unstable central nervous system metastases.

*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. 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 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	○ 17	○ 18	○ 19	○ 20
○ 21	○ 22	○ 23	○ 24	○ 25	○ 26	○ 27
○ 28	○ 29	○ 30	○ 31	○ 32	○ 33	○ 34

f. If yes, 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	○ 9	○ 10	○ 11	○ 12	○ 13
○ 14	○ 15	○ 16	○ 17			

4. Funded Dose

Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks, or pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks, given in combination with chemotherapy.

Treatment should continue until disease progression or unacceptable toxicity up to a maximum of 2 years (i.e., 35 doses given every 3 weeks, or 18 doses given every 6 weeks), whichever occurs first.

[ST-QBP regimen code(s): CRBPGEMC(W)+PEMB, PACL(W)+PEMB]

5. Notes

1. Patients who complete 2 years of pembrolizumab may continue with chemotherapy in the presence of clinical benefit as per physician discretion.

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

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

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

   Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:

   - A clinic note and imaging (if applicable) from treatment initiation, and
   - The most recent clinic note and imaging (if applicable)

   Please note: Patients who meet the NDFP eligibility criteria and are enrolled in the manufacturer's patient support program (PSP) are eligible to receive continued drug supply through the PSP until **September 6, 2023, inclusive**.

   For patients enrolled in the PSP and receiving the PSP-supplied drug in a private infusion clinic, these patients can be transitioned to the hospital or cancer centre and continue to receive PSP-supplied drug until **September 6, 2023**. The hospital or cancer centre should coordinate the supply of PSP-supplied drug between the PSP and their respective sites, if not done so already.

   After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date 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 under this policy. Regardless of the patient's prior funding source or prior dosing, NDFP will fund the weight-based dosing as indicated in the Funded Dose section above.

   The NDFP will fund a total duration of 35 doses given every 3 weeks or 18 doses given every 6 weeks, regardless of funding source.

3. **My patient is currently receiving chemotherapy for metastatic TNBC, can pembrolizumab be added?**

   Provided the patient is receiving first-line treatment for metastatic TNBC, the eligibility criteria were met at the time of chemotherapy 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).

4. **My patient received pembrolizumab in the neoadjuvant and adjuvant settings for high-risk early-stage TNBC. Will my patient be eligible for pembrolizumab funding in the metastatic setting?**

   Patients will be eligible provided the patient's disease recurred 6 months or more from the completion of curative intent treatment with pembrolizumab and they meet the eligibility criteria outlined in this policy.

5. **My patient is experiencing intolerable toxicities to chemotherapy. Will pembrolizumab continue to be funded if chemotherapy was discontinued?**

Patients who discontinue chemotherapy due to toxicity may continue with pembrolizumab as a single agent to complete 2 years' worth of treatment, provided the patient continues to have at least stable disease.

6. **My patient completed their initial course of pembrolizumab for locally recurrent unresectable or metastatic TNBC and did not experience disease progression or intolerance. At the time of disease recurrence, would my patient be eligible for retreatment?**

   At the time of confirmed disease recurrence, retreatment with pembrolizumab may be funded for up to an additional 1 year (i.e., up to 17 additional doses every 3 weeks or 9 additional doses every 6 weeks) provided pembrolizumab was not previously discontinued due to disease progression and no other systemic treatment was given in between. Patients retreated with pembrolizumab may receive chemotherapy at the discretion of the treating physician. Claims should be submitted under the same enrolment form used for initial treatment.

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:

- Pathology report(s) confirming TNBC (as per ASCO/CAP guidelines) and PD-L1 CPS ≥ 10.
- Clinic notes outlining patient and treatment history/response.
- CT scans every 3 to 6 months indicating no disease progression.
- Instances where there is pseudoprogression:
  - Clinic note documenting the assessment and decision to continue, AND
  - Confirmatory scan conducted preferably at 6 to 8 weeks but no later than 12 weeks after the initial disease progression to confirm the absence of true progression.

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

....
Day Month Year