Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - Advanced Melanoma (Unresectable or Metastatic Melanoma) and No Prior Ipilimumab

(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)

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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

The patient must meet the following criteria:

- Pembrolizumab is used for the treatment of adult patients with advanced melanoma (unresectable or metastatic melanoma). ☐ Yes
- Patients are naïve to ipilimumab treatment (patients with BRAF mutation positive may or may not have received BRAF targeted therapy).
- Treatment should be for patients with an ECOG performance status of 0 or 1, and who have stable brain metastases (if present).

3. Baseline Information

a. Disease Status
- ○ Unresectable Stage III
- ○ Stage IV

b. BRAF V600 mutation status
- ○ Positive ○ Negative
- ○ Unknown

c. The patient has received the following prior to pembrolizumab (check all that apply):
- ☐ BRAF inhibitor ☐ MEK inhibitor
- ☐ No prior treatment

d. ECOG PS at the time of enrolment
- ○ 0 ○ 1

e. The patient has stable brain metastases
- ○ Yes
- ○ Not applicable, the patient does not have brain metastases

4. Funded Dose

- Pembrolizumab 2mg/kg given once every 3 weeks as an intravenous infusion, up to a maximum of 200 mg per dose.
- Treatment should be continued until disease progression or to a maximum of 24 months' worth of equivalent therapy, whichever comes first.

5. Notes

1. Patients who have received ipilimumab before the effective funding date of pembrolizumab (i.e., received at least one treatment of ipilimumab prior to June 2, 2016) will be eligible to receive pembrolizumab upon disease progression.
2. Pembrolizumab funding is for single agent use only.
3. Pembrolizumab is not funded for patients who have confirmed disease progression while receiving a prior anti-PD-1 inhibitor in the metastatic setting.
4. Patients whose disease relapses at least 6 months after completing adjuvant anti-PD-1 inhibitor may be eligible for combination ipilimumab and nivolumab in the metastatic setting or, if the patient is unfit for combination immunotherapy, single agent immunotherapy.
5. For patients completing or stopping single agent pembrolizumab without disease progression, resumption of treatment will be funded provided no other treatment is given in between. Pembrolizumab funding is for a total of 24 months' worth of therapy or until confirmed disease progression, whichever occurs first. Pembrolizumab retreatment, for up to an additional 12 months' worth of therapy, can be considered at the point of confirmed disease progression (see FAQ #7). Claims should be submitted under the same form used for initial treatment.
6. For patients treated with anti-PD-1 monotherapy (instead of combination nivolumab plus ipilimumab) in the metastatic setting, ipilimumab monotherapy will be funded as a subsequent line of therapy provided that funding criteria are met.
7. Patients with BRAF mutation may be initiated on BRAF targeted therapy or immunotherapy. Upon disease progression, the patient may be switched to the other treatment modality as a subsequent line of therapy.

6. FAQs

i. ***My patient is currently receiving pembrolizumab through private means. Can my patient be transitioned over to receive funding through the New Drug Funding Program?***

   For patients currently enrolled in a patient assistance program, please contact your patient assistance program representative for more direction.

ii. ***My patient has recently completed ipilimumab treatments. Upon disease progression, will my patient be eligible for pembrolizumab?***

   Patients who have received ipilimumab before the effective funding date of pembrolizumab (i.e., received at least one treatment of ipilimumab prior to June 2, 2016) will be eligible to receive pembrolizumab upon disease progression.

iii. ***How does this drug/regimen relate to other funded agents for advanced melanoma?***

   The funding algorithm for typical reimbursement pathways for advanced melanoma are posted on the eClaims Resource Library.

iv. ***Patients may often be switched from targeted therapies (e.g., dabrafenib-trametinib) to immunotherapy (e.g., pembrolizumab) prior to disease progression as a best practice maneuver (saving the BRAF inhibitor for later), due to side effects or due to partial response. Upon disease progression of the immunotherapy, the patient may be treated with targeted therapy (e.g., dabrafenib-trametinib) again. Will the latter be funded?***

   It is noted that there are ongoing trials investigating the above sequence. Until there is further mature evidence available and a formal evaluation conducted to confirm clinical and cost-effectiveness, there will be no additional funding of the targeted therapy once the patient stops the initial targeted therapy and moves on to the immunotherapy or to another agent.

   If the patient was initially treated with pembrolizumab and experiences side effects that require a treatment break, the continuation of pembrolizumab will be funded provided that no other treatment is given in between. Funding will be for the remaining doses of pembrolizumab that would normally be given within a 24 month period.

v. ***My patient is showing evidence of disease progression after 14 doses of nivolumab. My patient does not have***

the BRAF mutation. Given her age and frailty, I would like to treat her with pembrolizumab. Will pembrolizumab be funded?

Pembrolizumab will not be funded. Although there are no head-to-head trials comparing nivolumab to pembrolizumab, both PD-1 inhibitors are considered to be clinically equivalent. If disease progression has occurred, there is no evidence to support the switch to pembrolizumab.

vi. ***My patient's disease has progressed on first line pembrolizumab. Will CCO fund subsequent ipilimumab?***

For patients treated with anti-PD-1 monotherapy in the metastatic setting, ipilimumab monotherapy will be funded as a subsequent line of therapy provided that funding criteria are met.

vii. ***My patient completed their initial course of pembrolizumab for advanced melanoma. Would they be eligible for retreatment?***

At the time of confirmed disease progression, retreatment with pembrolizumab, for up to an additional 12 months' worth of therapy, can be considered for patients who experienced stable disease or better, and received up to (and including) 24 months of treatment or for patients who stopped treatment due to complete response and then subsequently progressed.

viii. ***Will the maximum dose cap of 200 mg apply for all patients?***

As of the April 14, 2020 funding announcement, all new patients enrolling onto this policy will have their weight-based dose capped at 200 mg. Existing patients on their initial course of therapy may continue on their current dose until they have completed a total of 24 months' worth of therapy or until confirmed disease progression, whichever occurs first. This would also apply to patients who may be eligible for pembrolizumab retreatment.

7. Supporting Documents

None required for this policy.
In the absence of collecting supporting documentation:

- CCO reserves the right to perform an audit of patient eligibility.
- In the event of an audit, CCO may request the following:
    - CT scans every 3 to 6 months, along with clinic notes confirming no disease progression.
    - In instances where there is pseudoprogression, a clinic note documenting the assessment and decision to continue, and the subsequent CT scan confirming no disease progression.

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

....
Day Month Year