Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Ipilimumab - Previously Treated Advanced Unresectable Melanoma

(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)

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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

Please select one of the following criteria and answer the following questions:

Initial Treatment: Patient has unresectable Stage III or IV melanoma and has received at least one systemic therapy for advanced melanoma; the patient has an ECOG performance score ≤ 1 ○ Yes

Re-induction: At the time of disease progression, the patient has had stable disease for at least three months or has previously experienced a complete or partial response to ipilimumab; the patient has an ECOG performance score ≤ 1 ○ Yes

3. Baseline Information

a. ECOG performance status at the time of enrolment ○ 0 ○ 1

b. For initial treatment, select patient's previous treatments (check all that apply):
- ☐ BRAF and/or MEK inhibitor
- ☐ Nivolumab ☐ Pembrolizumab
- ☐ Other

  - If other, please specify: .....

c. For re-induction, select patient's condition at the time of disease progression (check all that apply):
- ☐ Stable disease for at least 3 months
- ☐ Previously experienced a complete or partial response to ipilimumab

4. Funded Dose

- Induction/Re-induction: Ipilimumab 3mg/kg every 3 weeks for 4 doses

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. If patient has received ipilimumab funding in the first-line setting, they will not be eligible for ipilimumab funding for re-induction or in subsequent lines of therapy.
3. Ipilimumab is not funded if the patient has an ECOG ≥ 2.
4. 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.
5. 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. Supporting Documents

None required for this policy.

In the absence of collecting supporting documentation:

- CCO reserves the right to perform an audit on the patient's eligibility to receive reimbursement for this policy
- In the event of an audit, CCO may request a clinic note demonstrating:
    - The patient's stable disease for at least three months of previous partial/complete response, and the patient has ECOG ≤ 1

CCO reserves the right to recover the cost of treatment claims if the requested documentations are not provided.

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

....
Day Month Year