

Ipilimumab - Previously Untreated 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 (m²): * 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:

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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

For the first-line treatment of patients who are at least 18 years old with advanced melanoma (i.e. primary cutaneous unresectable Stage IIIC or IV melanoma or metastatic melanoma), regardless of BRAF mutation status, who have an ECOG Performance Status less than or equal to 1, and are not currently receiving immunosuppressive therapy.

If a patient has brain metastasis, then they must be asymptomatic or stable.

3. Baseline Information

Please answer the following questions:

- | | |
|--|--|
| a. Patient is at least 18 years old with advanced melanoma (i.e. primary cutaneous unresectable Stage IIIC or IV melanoma or metastatic melanoma. Specify stage: | <input type="radio"/> Stage IIIC
<input type="radio"/> Stage IV |
| b. ECOG Performance Status at the time of enrolment | <input type="radio"/> 0 <input type="radio"/> 1 |
| c. Patient is not currently receiving immunosuppressive therapy | <input type="checkbox"/> Yes |
| d. Does patient have brain metastasis? | <input type="radio"/> Yes <input type="radio"/> No |
| • If patient has brain metastasis, they must be asymptomatic or stable | <input type="checkbox"/> Yes |

3. Funded Dose

- Ipilimumab 3mg/kg every 3 weeks for 4 doses

4. 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 in the first-line setting, they will not be eligible for ipilimumab funding for re-induction or in subsequent lines of therapy (NDFP Policy: Previously Treated Advanced Unresectable Melanoma)
3. Requests for dose escalation up to 10 mg/kg will not be considered
4. Maintenance or re-induction requests in the first line setting will not be considered

5. Supporting Documents

None required for this policy.

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

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Day Month Year