Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab and Relatlimab - Advanced Melanoma (Unresectable or Metastatic Melanoma)

(This form should 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

Nivolumab and Relatlimab will be used in pediatric or adult patients as treatment for unresectable stage III or metastatic (stage IV) melanoma. ☐ Yes

Patients must:

- Be previously untreated or have received prior first-line BRAF-targeted therapy for unresectable or metastatic melanoma
- Be 12 years of age or older
- Weigh over 40 kilograms
- Have a good performance status

Patient must not have:

- Active brain metastases
- Uveal melanoma
- Active autoimmune disease

3. Baseline Information

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

b. Disease Stage
○ Unresectable stage III
○ Stage IV

c. Does the patient have stable brain metastases?
○ Yes
○ Not applicable, the patient does not have brain metastases

d. BRAF V600 mutation status ○ Positive ○ Negative
○ Unknown

If BRAF positive, has the patient been treated with a BRAF and/or MEK inhibitor? ○ Yes ○ No

e. Is the patient transitioning from a private pay or compassionate program? ○ Yes ○ No

f. If yes, please indicate the funding source
○ Private payer
○ Manufacturer patient support program

g. If yes, please indicate the date of the last administered dose _____ Day _____ Month _____ Year

4. Funded Dose

Nivolumab 480 mg and relatlimab 160 mg as a fixed dose combination intravenously (IV) every 4 weeks

Treatment should continue until disease progression or unacceptable toxicity, whichever comes first.

[ST-QBP regimen code(s): NIVL+RELA]

5. Notes

1. Opdualag® is a fixed-dose combination product containing two drugs (nivolumab and relatlimab) in one IV dosage form.
2. Patients whose disease relapses at least 6 months after completing (neo)adjuvant anti-PD-1 therapy may be eligible for nivolumab with relatlimab in the metastatic setting, provided all other eligibility criteria are met.
3. Patients who have confirmed disease progression on prior anti-PD-1 therapy will not be eligible for nivolumab and relatlimab in the metastatic setting.
4. Patients who took a treatment break may reinitiate treatment provided they did not experience disease progression or unacceptable toxicity while on treatment.
5. Patients with a BRAF V600 mutation who are previously untreated or initiated on first-line BRAF targeted therapy may be eligible provided they meet the criteria outlined in this policy.

6. FAQs

1. **My patient is currently receiving nivolumab and relatlimab through non-publicly funded means (e.g.private insurance). Can my patient be transitioned 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 continued coverage 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).

3. **The calculated dose of Opdualag® will have two components (nivolumab and relatlimab). For the purposes of reimbursement, which component of Opdualag® do I submit to eClaims (i.e. the nivolumab dose, the relatlimab dose, or both doses)?**

   In order to receive the correct reimbursement for the dose administered, please submit the administered dose using the **nivolumab component only**. Sites should not submit the relatlimab component. Similarly, sites should not submit the sum of the nivolumab component plus the relatlimab component to eClaims.

4. **Opdualag® is a combination of two medications in one intravenous formulation. Will the reimbursement price reflect the nivolumab or the relatlimab component or both?**

   The Provincial Drug Reimbursement Program's reimbursement price (in cost per milligram) will be based on the **nivolumab component** to cover both components.

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:

- Clinic notes outlining patient and treatment history/response (if applicable).
- CT scans demonstrating no disease progression on treatment.

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

23 (Day) 10 (Month) 2024 (Year)

Form 1076