Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab - Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck, which is Platinum Resistant or Refractory

(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:

Nivolumab is used for the treatment of patients with squamous cell cancer of the head and neck (SCCHN) who either:
have a recurrence within 6 months of potentially curative neoadjuvant/adjuvant platinum-based therapy;
or, have a recurrence after receiving platinum-based therapy in a non-curative setting;
and have good performance status.

☐ Yes

Treatment should continue until confirmed disease progression or unacceptable toxicity.

3. Baseline Information

a. ECOG performance status at the time of enrolment

○ 0 ○ 1 ○ 2

b. HPV status

○ positive ○ negative ○ unknown

c. Select the statement that best describes your patient:

○ (i) ○ (ii) ○ (iii)

i. The patient's disease recurred within 6 months of potentially curative neoadjuvant/concurrent/adjuvant platinum-based therapy;
ii. The patient's disease progressed after receiving platinum-based therapy in a non-curative (i.e., palliative) setting;
iii. The patient has a documented intolerance or contraindication to platinum-based therapy and is being treated with palliative intent. A clinic note describing the intolerance or contraindication and confirming the treatment intent (i.e., palliative) has been uploaded.

4. Funded Dose

- Nivolumab 3 mg/kg IV, up to a maximum dose of 240 mg, every 2 weeks as an intravenous infusion, or nivolumab 6 mg/kg IV, up to a maximum dose of 480 mg, every 4 weeks as an intravenous infusion.

5. Notes

1. Patients who have disease progression more than 6 months following platinum-based chemotherapy should be retreated with a platinum-based therapy* (unless there is a documented intolerance or contraindication [see Note 2]), and then qualify for nivolumab upon disease progression. (*funded by ST-QBP if evidence-informed)
2. Patients with a documented intolerance or contraindication to platinum-based therapy and being treated with palliative intent will be eligible to receive coverage for nivolumab.
3. The patient is no longer eligible for nivolumab once there is confirmed disease progression.
4. Nivolumab is not funded for patients who have confirmed disease progression after receiving a prior anti-PD-1 inhibitor in the metastatic setting.
5. Nivolumab funding is for single agent use only.

6. FAQs

1. **My patient is currently receiving nivolumab through private means. Can my patient be transitioned over to receive funding through the New Drug Funding Program (NDFP)?**

   Provided the funding 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 nivolumab through the New Drug Funding Program.

2. **My patient's disease had recurred within 6 months after receiving a platinum-regimen concurrently with radiation. Is my patient eligible for nivolumab?**

   CCO will fund nivolumab provided that
   - The patient's disease recurred within 6 months of potentially curative neoadjuvant/ concurrent/or adjuvant platinum-based therapy; or
   - The patient's disease progressed after receiving platinum-based therapy in a non-curative (i.e., palliative) setting;
   - The patient has a documented intolerance or contraindication to platinum-based therapy and is being treated with palliative intent. A clinic note describing the intolerance and confirming the treatment intent (i.e., palliative) needs to be uploaded to eClaims.

3. **My patient is currently receiving nivolumab on an every 2 week schedule. Can my patient be transitioned over to the every 4 week schedule?**

   The decision to switch should be based on a discussion between the clinician and patient. Switches between schedules (from every 2 weeks to every 4 weeks or vice versa) will be eligible for continued funding provided the patient's disease has not progressed.

7. Supporting Documents

Initial enrolment:

- For patients with a documented intolerance or contraindication to platinum-based chemotherapy, a clinic note describing the nature of the intolerance or contraindication and confirming that the patient is being treated with palliative intent needs to be uploaded to eClaims.

In the event of an audit, the following should be available to document eligibility:

- CT scans every 3 to 6 months, along with clinic notes indicating no disease progression.
- In instances where there is pseudoprogression,
    - a clinic note **documenting** the assessment and decision to continue, AND
    - a 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 (i.e., an additional 10% in tumour burden and/or development of new lesions since the time of initial disease progression).

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

....
Day Month Year