Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab - Adjuvant Treatment of Completely Resected Esophageal or Esophagogastric Junction Cancer

(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)

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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 adjuvant treatment of completely resected esophageal or esophagogastric junction (EGJ) cancer in patients who have residual pathologic disease following prior neoadjuvant chemoradiotherapy (CRT). ☐ Yes

3. Baseline Information

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

b. The patient has advanced
- ○ Esophageal adenocarcinoma
- ○ Esophageal squamous cell carcinoma
- ○ EGJ adenocarcinoma
- ○ EGJ squamous cell carcinoma

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

d. If yes to 3c, how many treatments of every 2 week nivolumab did the patient have prior to transitioning to public funding?

○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8
○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ 15 ○ 16 ○ 17
○ 18 ○ 19 ○ 20 ○ 21 ○ 22 ○ 23 ○ 24 ○ 25

e. If yes to 3c, how many treatments of every 4 week nivolumab did the patient have prior to transitioning to public funding?

○ N/A ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8
○ 9 ○ 10 ○ 11 ○ 12

4. Funded Dose

Nivolumab 3 mg/kg intravenously (IV) every 2 weeks (up to a maximum dose of 240 mg); or nivolumab 6 mg/kg IV every 4 weeks (up to a maximum dose of 480 mg).

Treatment with nivolumab should be initiated within 4 to 16 weeks of complete resection.

Treatment should continue until disease progression or unacceptable toxicity to a maximum of 1 year, whichever comes first.

[ST-QBP regimen code: NIVL]

5. Notes

1. Nivolumab should not be used in combination with other adjuvant anti-cancer drugs.

2. Patients who receive adjuvant therapy with an immune checkpoint inhibitor, may be eligible for nivolumab or pembrolizumab in combination with chemotherapy in the advanced setting provided there was a disease-free interval (DFI) of 6 months or greater after the completion of adjuvant therapy, and all other eligibility criteria are met.

6. FAQs

i. **My patient is currently receiving nivolumab for esophageal or EGJ carcinoma that is paid for privately (e.g., patient support program, private insurance, etc.). 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 of nivolumab through the NDFP. Please submit as a prior approval request in eClaims including the most recent clinic note (outlining the response to treatment, if able to assess) and the number of nivolumab treatments received to date.

Based on CADTH recommendations, Ontario Health (Cancer Care Ontario) does not reimburse hospitals for nivolumab given as a "fixed" or "flat" dose (e.g., 240 mg IV every 2 weeks or 480 mg IV every 4 weeks). Regardless of the patient's prior funding source or prior dosing, the NDFP funded dose is nivolumab 3 mg/kg IV given every 2 weeks, up to a maximum of 240 mg per dose (or 6 mg/kg given every 4 weeks, up to a maximum of 480 mg per dose), and the funding duration is for a maximum of 1 year.

ii. **If treatment interruption occurs, should the remainder of the doses be given even if it will take more than a year to deliver treatments, provided there has been no disease progression?**

Nivolumab can be interrupted or delayed for a maximum of 10 weeks.

iii. **My patient is currently receiving nivolumab on an every 2 week schedule. Can my patient be transitioned over to an 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. Please note that the funded duration remains the same (i.e., a maximum of one year).

Supporting Documents

The following clinical document(s) must be uploaded at the time of enrolment:

- Surgical pathology report indicating residual pathologic disease with a tumour and node classification of ypT1 or ypN1, at minimum, following prior neoadjuvant chemoradiotherapy.

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

- Clinic notes demonstrating treatment history.
- CT scans every 3 to 6 months, along with clinic notes indicating no disease progression.

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

Day Month Year

Form 976