Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab - First-line Treatment of Advanced Gastric, Esophageal, and Esophagogastric Junction Adenocarcinoma

(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 in combination with fluoropyrimidine- and platinum-based chemotherapy for the first-line treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic gastric, esophagogastric junction (EGJ), or esophageal adenocarcinoma. ☐ Yes

3. Baseline Information

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

b. The patient has advanced unresectable or metastatic
- ○ Gastric adenocarcinoma
- ○ Adenocarcinoma of the EGJ
- ○ Esophageal adenocarcinoma

c. The patient has stable brain metastases
- ○ Yes
- ○ Not applicable, the patient does not have brain metastases

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

e. If yes to 3d, was the patient on an every 2 week dosing schedule of nivolumab? ○ Yes ○ No

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

○ 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	○ 26	○ 27
○ 28	○ 29	○ 30	○ 31	○ 32	○ 33	○ 34	○ 35	○ 36
○ 37	○ 38	○ 39	○ 40	○ 41	○ 42	○ 43	○ 44	○ 45
○ 46	○ 47	○ 48	○ 49	○ 50	○ 51			

g. If no to 3e, how many treatments of every 3 week nivolumab did the patient have prior to transitioning to public funding?

○ 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	○ 26	○ 27
○ 28	○ 29	○ 30	○ 31	○ 32	○ 33	○ 34		

4. Funded Dose

Nivolumab 3 mg/kg given intravenously (IV) (up to a maximum of 240 mg) every 2 weeks; or
Nivolumab 4.5 mg/kg given IV (up to a maximum of 360 mg) every 3 weeks.

Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years, whichever comes first.

[ST-QBP regimen codes: CISPFU+NIVL, CRBPFU+NIVL, CAPECISP+NIVL, CAPECRBP+NIVL, MFOLFOX6+NIVL, or XELOX+NIVL, NIVL(MNT)].

5. Notes

1. NDFP will only fund one of nivolumab or pembrolizumab for the first-line treatment of gastric, EGJ, or esophageal cancer in the advanced setting. Please note the following:
    - Only pembrolizumab can be funded for squamous cell carcinoma of the esophagus.
    - Only nivolumab can be funded for gastric adenocarcinoma.
    - For patients who are a candidate for either therapy (esophageal or EGJ adenocarcinoma), the decision is up to the treating physician.

2. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 years' worth of treatment with nivolumab, with or without chemotherapy, at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment and provided that no other systemic treatment is given in between. Claims should be submitted under the same form used for the initial course of treatment.

3. At least 1 cycle of chemotherapy must be given concurrently with nivolumab before changing to nivolumab maintenance due to intolerance.

4. Patients who received prior adjuvant therapy with an immune checkpoint inhibitor may be eligible for nivolumab in combination with chemotherapy in the advanced setting provided there was a disease-free interval (DFI) of 6 months or greater after completing adjuvant therapy.

6. FAQs

i. **My patient is currently receiving nivolumab for gastric, esophageal or EGJ adenocarcinoma 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). 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 4.5 mg/kg given every 3 weeks, up to a maximum of 360 mg per dose), and the funding duration is for a total of 2 years' worth of treatment for the initial course.

ii. **My patient is awaiting human epidermal growth factor receptor 2 (HER2) test results. Can we start therapy with nivolumab and chemotherapy in the interim?**

Patients may initiate therapy with a platinum- and fluoropyrimidine-based chemotherapy regimen while awaiting HER2 test results.

iii. **My patient is receiving fluoropyrimidine- and platinum-based chemotherapy. Can nivolumab be added?**

Provided the patient has not progressed on treatment, and meets all the eligibility criteria, the addition of nivolumab may be funded under this policy. Please submit as a prior approval request in eClaims including the most recent clinic note outlining the treatment history and response to treatment, if able to assess.

iv. **My patient is currently receiving nivolumab on an every 2-week schedule. Can my patient be transitioned over to an every 3-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 3 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 two years for the initial treatment course plus one additional year of retreatment, if eligible).

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:

- Pathology report demonstrating HER2-negativity.
- Clinic notes documenting treatment history.
- 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 the subsequent CT scan confirming no disease progression.

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

....
Day Month Year

Form 975