Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab - Adjuvant Treatment of Urothelial Carcinoma

(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)

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 monotherapy is used as adjuvant therapy in adult patients* with urothelial carcinoma (UC) who are at high risk of recurrence after radical resection of UC. ☐ Yes

Treatment is only for patients who have no evidence of recurrence confirmed prior to initiating therapy, no metastatic disease or active autoimmune disease, and with good performance status.

Treatment should be initiated within 120 days of surgical resection.

*Eligible patients include those who have:

- muscle invasive urothelial carcinoma at diagnosis

AND

- received cisplatin-based neoadjuvant chemotherapy (ypT2-pT4a or ypN+) OR have not received neoadjuvant cisplatin chemotherapy (pT3-pT4a or pN+) and are ineligible or have declined adjuvant cisplatin-based chemotherapy.

3. Baseline Information

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

b. Is the patient receiving nivolumab from a non-publicly funded means? ○ Yes ○ No

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

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

e. If yes, how many doses of nivolumab given every 2 weeks did the patient receive prior to the transition?
○ 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

f. If yes, how many doses of nivolumab given every 4 weeks did the patient receive prior to the transition?
○ 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 of 240 mg) or nivolumab 6 mg/kg IV every 4 weeks (up to a maximum of 480 mg).

Treatment should continue until disease recurrence or unacceptable toxicity up to a maximum of 1 year (i.e., 26 doses of nivolumab if given every 2 weeks or 13 doses if given every 4 weeks), whichever comes first.

[ST-QBP regimen code: NIVL]

5. Notes

1. As per the pivotal trial, patients deemed ineligible for adjuvant cisplatin-based chemotherapy (as per the Galsky criteria) include those with:

    - Creatinine clearance (using the Cockcroft-Gault formula) less than 60 mL/min.
    - Common Terminology Criteria for Adverse Events (CTCAE) version 4, grade 2 or above audiometric hearing loss.
    - CTCAE version 4, grade 2 peripheral neuropathy.
    - New York Heart Association (NYHA) Class III or IV Heart Failure.

2. Patients with urethral tumors who are at high risk of recurrence after radical resection are eligible.

6. FAQs

i. **My patient is currently receiving nivolumab through non-publicly funded means (e.g., patient support program, private insurance, etc.). Can my patient be transitioned to receive funding for nivolumab 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.

Patients who meet the eligibility criteria may be transitioned to NDFP funding through a regular eClaims enrolment. If there is clinical uncertainty regarding eligibility, these requests may be submitted as a prior approval including a clinic note from the time of initiation as well as the most recent clinic note outlining the response to treatment (if able to assess).

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 every 2 weeks up to a maximum of 240 mg or nivolumab 6 mg/kg IV every 4 weeks up to a maximum of 480 mg, for a maximum funded duration of 1 year.

ii. **My patient had either a partial cystectomy or a partial nephrectomy (for renal pelvis tumors), or bladder-preserving chemoradiation. Would my patient be eligible for adjuvant nivolumab?**

Provided negative margins were achieved, patients who had undergone a partial cystectomy or partial nephrectomy would be eligible for funding. Conversely, patients who received bladder-preserving chemoradiation would not be eligible.

iii. **Are bladder cancers with histological subtypes other than urothelial carcinoma eligible for funding?**

Patients with other histological subtypes (or variants) are eligible provided the patient also has a urothelial component to the histology and meets all other eligibility criteria.

iv. **My patient experienced treatment interruptions or delays with nivolumab. Do all doses of nivolumab have to be administered within 1 year of initiation of therapy?**

In the absence of disease progression, NDFP will provide funding for a total of 26 doses of nivolumab if given every 2 weeks or 13 doses if given every 4 weeks, outside of the twelve sequential calendar months if the patient requires a treatment interruption or delay (up to a maximum of 2 years).

v. **My patient was treated with nivolumab for UC in the adjuvant setting, will they be eligible for downstream funding of an anti-PD-1/PD-L1 agent in the advanced or metastatic setting?**

Patients who received a nivolumab in the adjuvant setting may be eligible for an anti-PD-1/PD-L1 agent in the advanced or metastatic setting provided that there was a disease-free interval (DFI) of 6 months or greater from the last adjuvant dose.

7. 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 note(s) documenting the patient's treatment history and response.
- Pathology report confirming muscle-invasive UC at disease diagnosis.
- Surgical pathology report confirming disease staging and histology.
- CT scans every 3 to 6 months indicating no disease progression.
- Instances where there is pseudoprogression:
    - Clinic note documenting the assessment and decision to continue, AND
    - 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.

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

....
Day Month Year

Form 1012