Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Nivolumab plus Ipilimumab – Metastatic Renal Cell 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
- ○ 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:

- Combination nivolumab plus ipilimumab is used for the treatment of previously untreated patients with intermediate or poor-risk advanced renal cell carcinoma based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria. ☐ Yes

3. Baseline Information

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

b. Please select the patient's risk stratification: ○ Intermediate ○ Poor

c. Tumour histologic type ○ Clear cell ○ Non-clear cell

d. The patient is transitioning from the OLYveR program ○ Yes ○ No

4. Funded Dose

Nivolumab 3mg/kg and ipilimumab 1mg/kg every three weeks for up to four doses (ST-QBP regimen code: NIVL+IPIL), followed by

- Nivolumab maintenance at 3mg/kg up to a maximum of 240mg every two weeks (ST-QBP regimen code: NIVL(MNT))

  or
- Nivolumab maintenance at 6mg/kg up to a maximum of 480mg every four weeks (ST-QBP regimen code: NIVL(MNT)).

Patients enrolling in this policy must be able to initiate treatment with nivolumab and ipilimumab at the same time.

Treatment with combination nivolumab plus ipilimumab (followed by nivolumab maintenance) should be continued until unacceptable toxicity or confirmed disease progression.

5. Notes

1. Patients who have progressed on prior therapies in the metastatic setting (e.g. tyrosine kinase inhibitors) are not eligible for combination nivolumab plus ipilimumab.

2. For patients who stop nivolumab maintenance without disease progression, continuation of maintenance nivolumab will be funded provided that no other treatment is given in between.

3. Patients who progress on treatment with combination nivolumab plus ipilimumab (or nivolumab maintenance) will not be eligible for single agent nivolumab in subsequent lines of therapy.

4. Completion of this form will automatically enroll the patient for both nivolumab and ipilimumab.

6. Supporting Documents

For patients transitioning from the OLYveR program, please upload a recent clinic note and recent CT scan (if available) to confirm lack of disease progression.

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

- Clinic note indicating the patient's risk stratification
- CT scans every 3 to 6 months, along with clinic notes confirming 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.

7. FAQs

i. My patient is currently receiving combination nivolumab plus ipilimumab 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 combination nivolumab plus ipilimumab through NDFP.

If your patient previously received treatment through the OLYveR program and is now on maintenance nivolumab, please use this enrolment form to submit treatments.

ii. My patient has good risk disease, but I would like to treat them with combination nivolumab plus ipilimumab. Will this be funded?

NDFP will only fund combination nivolumab plus ipilimumab for patients with intermediate or poor-risk disease as per the IMDC criteria.

iii. My patient progressed on a prior therapy for mRCC. Can I treat them with combination nivolumab plus ipilimumab now?

Patients whose disease has progressed on any prior therapy for mRCC in the metastatic setting (regardless of the timing of progression) are not eligible for combination nivolumab plus ipilimumab.

Single agent nivolumab remains as a treatment option for patients who are not eligible for combination immunotherapy and meet all funding criteria for the selected policy (eClaims policy titles – 'Nivolumab - Advanced or Metastatic Renal Cell Carcinoma and No Prior mTOR Inhibitor' or 'Nivolumab - Advanced or Metastatic Renal Cell Carcinoma and Prior mTOR Inhibitor').

iv. My patient had to take a treatment break from combination nivolumab plus ipilimumab. Is retreatment funded?

Retreatment with combination nivolumab plus ipilimumab is not funded if the patient completed a course of induction. However, your patient may be eligible for continuation of nivolumab maintenance provided that no other treatment is given in between.

v. I would like to start my patient on nivolumab and add ipilimumab at a later date. How do I enroll my patient?

Patients enrolling in this policy must be able to initiate treatment with both nivolumab and ipilimumab at the same time.

If your patient is not able to tolerate combination nivolumab plus ipilimumab at the time of treatment initiation, single agent nivolumab remains as a treatment option in the second or third line setting after failure of tyrosine kinase inhibitor (TKI) therapy.

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

....
Day Month Year