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Eligibility Form

Pembrolizumab - In Combination with Platinum and Pemetrexed for First Line Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC)

(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

The patient must meet the following criteria:

- Pembrolizumab is used in combination with pemetrexed and platinum chemotherapy for the treatment of metastatic non-squamous, non-small cell lung cancer (NSCLC), in adult patients with no EGFR or ALK genomic tumour aberrations, and no prior systemic chemotherapy treatment for metastatic NSCLC. ☐ Yes

  Treatment should be for patients with good performance status.

3. Baseline Information

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

b. PD-L1 expression level ○ Not tested ○ <1% ○ 1-49% ○ >=50%

4. Funded Dose

Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or
Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days.

Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first.

Pembrolizumab must be given in combination with pemetrexed and platinum (cisplatin or carboplatin) for the first 4-6 cycles, followed by pemetrexed only for the maintenance phase. [ST-QBP regimen code: CISPPEME+PEMB or CRBPPEME+PEMB for induction phase, PEME+PEMB(MNT) for maintenance phase]

5. Notes

1. The cost of pemetrexed-based induction and pemetrexed maintenance as part of this regimen for non-squamous non-small cell lung cancer (NSCLC) is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.
2. Ontario Health (Cancer Care Ontario) will fund one line of anti-PD1/PD-L1 therapy for advanced non-small cell lung cancer. Patients who were treated with (neo)adjuvant anti-PD1/PD-L1 therapy in the curative setting must have a disease-free interval of 6 months or greater in order to be considered for funding under this policy.
3. For patients who stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete 2 years' worth of treatment) will be funded provided that no other treatment is given in between.
4. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 year's worth of treatment at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same enrolment form used for initial treatment.

6. FAQs

1. **My patient is currently receiving pembrolizumab through non-publicly funded 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 pembrolizumab through the New Drug Funding Program.

   At the NDFP funded dose of 2 mg/kg (up to a maximum of 200 mg per dose) or 4 mg/kg (up to a maximum of 400 mg per dose), funding is for a total of 2 years' worth of treatment for the initial course, regardless of the funding source.

2. **My patient is currently on platinum doublet without pembrolizumab. Can I add pembrolizumab to the treatment regimen?**

   Patients who have already initiated therapy with pemetrexed-platinum, as of the effective funding date, may add pembrolizumab to the treatment regimen provided all funding criteria for pembrolizumab are met.

   Patients who are currently being treated with pemetrexed maintenance are not eligible for the addition of pembrolizumab, but may be eligible for immunotherapy in a subsequent line of therapy.

3. **My patient is being treated with an alternate chemotherapy regimen. Can I add pembrolizumab to the treatment regimen?**

   Funding for pembrolizumab under this policy is specific to patients who are being treated with platinum and pemetrexed chemotherapy. Patients may be considered for pembrolizumab funding under this policy if they are eligible to initiate treatment with platinum and pemetrexed chemotherapy.

4. **My patient had to discontinue pemetrexed due to toxicity. Can I continue pembrolizumab as a single agent?**

   Patients who discontinue chemotherapy due to toxicity may continue with pembrolizumab as a single agent to complete 2 years' worth of treatment.

5. **My patient may not be able to tolerate both pembrolizumab and platinum doublet up front. Can I start my patient with pembrolizumab or platinum doublet and add the other part later?**

   Patients who are not able to tolerate therapy with an up front platinum doublet and pembrolizumab will not be funded for pembrolizumab under this policy. Front-line pembrolizumab monotherapy may be considered for patients who express PD-L1 ≥ 50%.

7. Supporting Documents

None required at the time of enrolment.

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 the subsequent CT scan confirming no disease progression.

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

Day Month Year

Form 957