Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

# Pembrolizumab - First Line Treatment of MSI-H/dMMR Metastatic Colorectal 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)

.....

**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 as monotherapy for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in patients with good performance status. ☐ Yes

## 3. Baseline Information

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

b. The patient has metastatic ____ cancer ○ Colon ○ Rectal ○ Small Bowel ○ Appendiceal

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

d. If yes, how many cycles did the patient have prior to the transition?

○ 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

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.

[ST-QBP regimen code: PEMB]

## 5. Notes

1. On a time-limited basis, the NDFP can consider requests for patients who missed the opportunity to access pembrolizumab as first-line treatment for MSI-H/dMMR metastatic colorectal cancer provided all other eligibility criteria are met. Please submit as a prior approval request including the most recent clinic note summarizing the patient's treatment history and the pathology report confirming MSI-H/dMMR status.

2. Patients with metastatic small bowel and appendiceal cancers who meet all other funding criteria may be considered for pembrolizumab funding under this policy.

3. For patients who temporarily stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete 2 years' worth of treatment) will be funded provided that no other systemic treatment is given in between.

4. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 years' worth of treatment with pembrolizumab monotherapy 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.

## 6. FAQs

i. **My patient is currently receiving pembrolizumab for MSI-H/dMMR metastatic colorectal cancer through non-publicly funded means. Can my patient be transitioned over 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 pembrolizumab 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 pathology report confirming MSI-H/dMMR status.

Based on CADTH recommendations, Ontario Health (Cancer Care Ontario) does not reimburse hospitals for pembrolizumab given as a "fixed" or "flat" dose (e.g., 200 mg IV every 3 weeks). Regardless of the patient's prior funding source or prior dosing, the NDFP funded dose is pembrolizumab 2 mg/kg IV given every 3 weeks, up to a maximum of 200 mg per dose (or 4 mg/kg given every 6 weeks, up to a maximum of 400 mg per dose), and the funding duration is for a total of 2 years' worth of treatment for the initial course (35 doses given every 3 weeks, or 18 doses given every 6 weeks), regardless of funding source.

ii. **My patient already initiated chemotherapy for first-line metastatic colorectal cancer and would like to switch to pembrolizumab. Will this be funded?**

Patients who have progressed following first-line therapy for metastatic colorectal cancer will not be funded for pembrolizumab under this policy.

Patients who receive alternate first-line therapy before MSI-H/dMMR results are available may be switched to pembrolizumab at the time MSI-H/dMMR status is confirmed. Please submit as a prior approval request, along with documentation assessing the patient's response to treatment.

iii. **My patient has progressed after receiving pembrolizumab for MSI-H/dMMR metastatic colorectal cancer. What can my patient receive as subsequent lines of therapy?**

Patients who receive pembrolizumab under this policy may be eligible to receive all other therapies currently funded by NDFP for metastatic colorectal cancer, provided all funding criteria are met under the selected policy (e.g. bevazicumab as part of combination therapy is eligible for funding in the second line setting after progression on first line pembrolizumab for MSI-H/dMMR colorectal cancer). Please refer to the respective policies for full funding criteria.

iv. **My patient is currently receiving pembrolizumab on an every 3 week schedule. Can my patient be transitioned over to an every 6 week schedule?**

The decision to switch should be based on a discussion between the clinician and patient. Switches between schedules (from every 3 weeks to every 6 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

Pathology report confirming MSI-H/dMMR status must be uploaded at the time of enrolment.
In the event of an audit, the following should be available to document eligibility:

- 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 961*