Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Ramucirumab - Advanced or Metastatic Gastric Cancer or Gastro-esophageal Junction Adenocarcinoma

(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

Request prior approval for enrolment

* Justification for Funding

2. Eligibility Criteria

The patient must meet the following criteria:

- Ramucirumab is used in combination with paclitaxel for the treatment of advanced or metastatic gastric cancer or gastro-esophageal junction (GEJ) adenocarcinoma with disease progression following first-line chemotherapy. ☐ Yes
- Treatment should be for patients with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.

3. Baseline Information

a. Site of primary tumour
- ○ Gastric
- ○ Gastro-esophageal junction

b. ECOG PS at the time of enrolment
- ○ 0
- ○ 1

c. Prior systemic treatments received for advanced or metastatic gastric cancer or gastro-esophageal adenocarcinoma. Check all that apply:
- ☐ Triplet: platinum and fluoropyrimidine with anthracycline
- ☐ Doublet: platinum and fluoropyrimidine
- ☐ Anti-HER2 agent (e.g., trastuzumab)
- ☐ Other

Specify: _____

4. Funded Dose

- Ramucirumab 8 mg/kg IV on days 1, 15 every 28 days until disease progression (to be used in combination with paclitaxel).

5. Notes

1. To be eligible for funding, patients must be able to start ramucirumab in combination with paclitaxel. Paclitaxel may be temporarily held due to toxicity or intolerance.
2. In the event that a patient has to discontinue paclitaxel due to toxicity or intolerance, ramucirumab will continue to be funded. Relevant documentation (e.g., clinic note) is required. If disease progresses while on single agent ramucirumab, further funding of ramucirumab will be discontinued.
3. The paclitaxel component (i.e., paclitaxel IV on days 1, 8, and 15) of this regimen is funded through the Systemic Treatment Quality-Based Program (ST-QBP). The regimen is evidence-informed in the palliative setting and is known by regimen code PACL(W)+RAMU. ST-QBP funds the drug cost and the delivery cost of paclitaxel plus the delivery cost of ramucirumab. NDFP funds the drug cost of ramucirumab provided the patient meets the eligibility criteria. There is no NDFP enrolment form for paclitaxel for this indication.

6. FAQs

i. **My patient is currently receiving ramucirumab 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 ramucirumab, when used in combination with paclitaxel, through the New Drug Funding Program.

ii. **Can I start my patient with single agent ramucirumab and add paclitaxel at a later date?**

Ramucirumab is not reimbursed if initiated as a single agent. Ramucirumab reimbursement is intended for use in combination with paclitaxel.

iii. **Can I give paclitaxel every 3 weeks (instead of weekly paclitaxel on days 1, 8, and 15) in combination with ramucirumab?**

The only regimen that will be funded is ramucirumab 8 mg/kg IV days 1, 15 in combination with paclitaxel 80 mg/m2 IV days 1, 8, 15, every 28 days (coded as PACL(W)+RAMU in the Systemic Treatment Quality-Based Program regimen list).

iv. **If my patient experiences intolerance/toxicity to paclitaxel and needs to discontinue paclitaxel, will single agent ramucirumab be reimbursed by NDFP in this clinical circumstance?**

Ramucirumab is not funded if your patient is unable to receive paclitaxel at the time of ramucirumab initiation.
If a patient needs to discontinue paclitaxel due to toxicity or intolerance, NDFP will continue to fund single agent ramucirumab.
If disease progression occurs while on a reduced regimen (i.e., single agent ramucirumab), your patient will no longer be eligible to receive funding for ramucirumab.

v. **Will ramucirumab be reimbursed if given in any other regimen?**

Ramucirumab is only funded if used in combination with paclitaxel based on the results of the RAINBOW study (Wilke et al., 2014)[i].

[i]Wilke H et al. Ramucirumab plus paclitaxel versus placebo plus paclitaxel in patients with previously treated advanced gastric or gastro-oesophageal junction adenocarcinoma (RAINBOW): a double-blind, randomized phase 3 trial. Lancet Oncol 2014; 15:1224-35.

7. Supporting Documents

None required for this policy.

In the absence of collecting supporting documentation at the time of enrolment:

- CCO reserves the right to perform an audit of patient eligibility.
- In the event of an audit, the following (but not limited to) should be available to confirm eligibility:
    - Medication administration records which document that ramucirumab was being given with paclitaxel
    - CT scans indicating stable disease (as per RECIST 1.1 criteria) approximately every 3 months while on treatment

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

....
Day Month Year