Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Raltitrexed - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer

(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 (comple 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 criteria "a" and at least one of criteria "b" or "c":

a. Raltitrexed will be used to treat patients with metastatic colorectal, small bowel, or appendiceal cancer ☐ Yes

b. The patient has complete dihydropyrimidine dehydrogenase (DPD) deficiency ○ Yes ○ No

c. The patient also
- ☐ has experienced unacceptable toxicity with fluorouracil chemotherapy, and/or
- ☐ lives more than 60 km from the treatment centre/hospital, and/or
- ☐ has special transportation needs (e.g., ambulance or special vehicle)

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. Raltitrexed will be used in combination with ○ N/A (using monotherapy) ○ Oxaliplatin ○ Irinotecan

d. If the patient has a complete DPD deficiency, please indicate both *DPYD* genetic variants ○ c.1905+1G>A (*2A) ○ c.1679T>G (*13) ○ c.1129-5923C>G, c.1236G>A (HapB3) ○ c.2846A>T ○ Other

If other, please specify _____

○ c.1905+1G>A (*2A) ○ c.1679T>G (*13) ○ c.1129-5923C>G, c.1236G>A (HapB3) ○ c.2846A>T ○ Other

If other, please specify _____

e. Is the patient transitioning from a non-publicly funded program? ○ Yes ○ No

f. If yes to 3e, please indicate the date of the last administered dose _____ Day _____ Month _____ Year

4. Funded Dose

Raltitrexed 3 mg/m^2 intravenously (IV) every 21 days.

Treatment should continue until disease progression or unacceptable toxicity, whichever comes first.

[ST-QBP regimen codes: RALT, OXALRALT, IRINRALT]

5. Notes

1. As per the Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline (2017), *DPYD* poor metabolizers are defined as a patient carrying two no function alleles OR a patient carrying one no function allele plus one decreased function allele. Patients with a *DPYD* poor metabolizer phenotype have complete DPD deficiency.

6. FAQs

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

5. Supporting Documents

None required at the time of enrolment.

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

- a clinic note detailing patient and treatment history/response.
- pharmacogenetic report showing *DPYD* genotyping result(s) including the specific variants (if applicable).

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

....
Day Month Year