

Raltitrexed - Adjuvant Esophageal, Gastroesophageal Junction, or Gastric 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 (m²): * 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:

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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:

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2. Eligibility Criteria

The patient must meet criteria "a" and at least one of criteria "b" or "c":

- a. Raltitrexed will be used as adjuvant therapy in patients with esophageal, gastroesophageal junction, or gastric 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 _____ cancer Esophageal Gastroesophageal junction
 Gastric
- c. Raltitrexed will be used in combination with N/A (using monotherapy)
 Oxaliplatin
- d. If the patient has a complete DPD deficiency, please indicate both *DPYD* genetic variants
- | | |
|---|---------------------------------------|
| <input type="radio"/> c.1905+1G>A (*2A) | <input type="radio"/> c.1679T>G (*13) |
| <input type="radio"/> c.1129-5923C>G, c.1236G>A (HapB3) | <input type="radio"/> c.2846A>T |
| <input type="radio"/> Other | |
- If other, please specify _____
- | | |
|---|---------------------------------------|
| <input type="radio"/> c.1905+1G>A (*2A) | <input type="radio"/> c.1679T>G (*13) |
| <input type="radio"/> c.1129-5923C>G, c.1236G>A (HapB3) | <input type="radio"/> c.2846A>T |
| <input type="radio"/> Other | |
- If other, please specify _____
- e. Is the patient transitioning from a non-publicly funded program? Yes No
- f. If yes, please indicate the date of the last administered dose _____
Day Month Year
- b. If yes, how many previous treatments did the patient receive?
 1 2 3 4 5 6 7

4. Funded Dose

Raltitrexed 3 mg/m² intravenously (IV) every 21 days.

Treatment should continue until disease progression, unacceptable toxicity or up to a maximum of 8 cycles, whichever comes first.

[ST-QBP regimen codes: RALT, OXALRALT]

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).

Of note, funding is for a total of 8 cycles, either as monotherapy or as combination therapy, regardless of funding source.

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.
- pharmacogenetic report showing *DPYD* genotyping result(s) including the specific variants (if applicable).

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

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Day Month Year