Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pralatrexate - Relapsed or Refractory Peripheral T-cell Lymphoma (PTCL)

(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
- ○ 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:

.....

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:

- Pralatrexate is used for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) who have undergone previous systemic treatment, none of which include romidepsin. ☐ Yes
- Treatment should be for patients with a good performance status.

3. Baseline Information

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

b. Is the patient transitioning from a private payer or compassionate program? ○ Yes ○ No

c. PTCL subtype?

○ PTCL (unspecified or NOS)
○ angioimmunoblastic T-cell lymphoma (AITL)
○ anaplastic large T-cell lymphoma
○ cutaneous gamma/delta T-cell lymphoma
○ hepatosplenic PTCL
○ enteropathy-associated T-cell lymphoma
○ extranodal natural killer/TCL nasal type
○ subcutaneous panniculitis-like TCL
○ transformed mycosis fungoides
○ other (prior approval required)

Other (specify): .....

4. Funded Dose

Pralatrexate 30 mg/m^2 intravenously (IV) once weekly for six weeks followed by one week off treatment (a seven week cycle) [ST-QBP regimen code: PRAL].

Treatment should continue until disease progression or unacceptable toxicity.

5. Notes

1. Patients will be eligible for either pralatrexate or romidepsin, but not both.
2. Vitamin supplementation is mandatory prior to the first dose of pralatrexate:
    i. Folic acid 1 to 1.25 mg orally once daily beginning 10 days prior to the first dose of pralatrexate and continuing for 30 days after the last dose;
    ii. Vitamin B12 1000 mcg intramuscularly within 10 weeks prior to the first dose of pralatrexate and continuing every 8 to 10 weeks thereafter during therapy.

6. FAQs

i. **My patient is currently receiving pralatrexate for relapsed or refractory PTCL 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 pralatrexate through NDFP.

ii. **Will alternative dosing schedules for pralatrexate be eligible for NDFP funding?**

Yes, as long as the alternative dosing schedule does not exceed the maximum funded single dose and/or schedule as outlined in the 'Funded Dose' section.

iii. **I have a CD30+ systemic anaplastic large cell lymphoma patient on brentuximab vedotin. Will my patient be eligible for pralatrexate funding upon disease progression?**

Pralatrexate (or romidepsin) funding is also available for patients with the systemic CD30+ anaplastic large cell lymphoma (ALCL) subtype of PTCL, provided funding criteria are met. No evidence exists to inform the optimal sequencing for brentuximab vedotin versus pralatrexate or romidepsin. The choice in sequencing should be based on a discussion between the treating hematologist and patient.

7. Supporting Documents

None required at time of enrolment.

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

- Clinic note detailing treatment history, including response to previous systemic treatment.
- Pathology report confirming the peripheral T-cell lymphoma subtype.

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

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Day Month Year