Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Romidepsin - Relapsed or Refractory Peripheral T-Cell Lymphoma

(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:

- For patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) who: ☐ Yes
  - are ineligible for transplant;
  - have undergone previous systemic therapy; and
  - have an Eastern Cooperative Performance Status (ECOG) of 0 to 2.

3. Baseline Information

a. Diagnosis

- ○ 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

b. Number of systemic* therapies received prior to romidepsin (*autologous stem cell transplant plus the salvage and conditioning chemotherapy is considered 1 line of therapy) .....

c. Treatments received prior to romidepsin (please select all that apply)

- ☐ CHOP
- ☐ CHOP-etoposide
- ☐ gemcitabine-based chemotherapy
- ☐ low-dose palliative chemotherapy
- ☐ other combination chemotherapy
- ☐ autologous stem cell transplant (includes salvage and conditioning chemotherapy)
- ☐ other

Other (specify): .....

d. ECOG PS at the time of enrolment ○ 0 ○ 1 ○ 2

e. Date of first romidepsin treatment

Day Month Year

4. Funded Dose

Romidepsin 14 mg/m^2 intravenously on days 1, 8 and 15 (cycle length is 28 days), until disease progression or unacceptable toxicity.

5. Notes

1. The following subtypes are eligible for romidepsin funding: 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.
2. Romidepsin funding does not apply to patients with **non**-transformed mycosis fungoides type of cutaneous T-cell lymphoma, Sezary syndrome, or patients with known CNS lymphoma.
3. The romidepsin eligibility criteria also applies to patients who have had prior stem cell transplant.
4. Brentuximab vedotin funding is also available for patients with the CD30+ systemic anaplastic large cell lymphoma subtype of peripheral T-cell lymphoma, 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.
5. Patients will be eligible for either pralatrexate or romidepsin, but not both.

6. FAQs

i. **My patient is currently receiving romidepsin 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 romidepsin through NDFP.

ii. **My patient has started a chemotherapy regimen and I would like to switch him to romidepsin. Would NDFP allow this switch?**

The decision to switch should be based on a discussion between the clinician and patient. Provided the patient meets the funding criteria, NDFP will fund the romidepsin after the switch.

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

Romidepsin (or pralatrexate) 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

A pathology report must be submitted outlining the diagnosis of peripheral T-cell lymphoma or the above listed subtypes.

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

....
Day Month Year

Form 829