Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Rituximab (Biosimilar IV) and Rituximab SC - Previously Untreated Chronic Lymphocytic Leukemia

(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:

Patient has previously untreated chronic lymphocytic leukemia where fludarabine-based therapy is considered appropriate. ☐ Yes

3. Baseline Information

a. Screening for Hepatitis B virus with HBsAg and HBcAb has been completed or is in progress ○ Yes ○ No

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

4. Funded Dose

- Cycle 1 – rituximab (biosimilar) 375 mg/m^2 intravenously (IV) (See Note 5)
- Cycles 2 through 6 – rituximab (biosimilar) 500 mg/m^2 IV or 1600 mg subcutaneously (SC) (fixed dose)

All patients must receive their first dose of rituximab (biosimilar) by IV administration prior to initiating rituximab SC.

5. Notes

1. For patients with high tumour load, consider a slower infusion rate or split dosing over 2 days during the first cycle.
2. Rituximab must be used with fludarabine-based chemotherapy. Patients who are receiving rituximab by subcutaneous administration must use fludarabine and cyclophosphamide.
3. Patients on current fludarabine-based therapy may receive rituximab provided they have not progressed on therapy.
4. The IV and SC formulations of rituximab are not interchangeable.
5. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given SC if the patient tolerated the first IV dose.

6. FAQs

i. **My patient is currently receiving rituximab IV. Can my patient be switched over to the SC formulation for the remainder of their treatment cycles?**

At the discretion of the treating physician, patients currently on rituximab IV may be switched over to the SC formulation for the remainder of the funded doses according to the specific policy.

If the patient is already enrolled in an NDFP policy for rituximab IV, please re-enroll the patient in the updated rituximab enrolment form in order to submit treatments for rituximab SC.

ii. **If my patient cannot tolerate rituximab SC, will NDFP fund a switch from SC to IV?**

At the discretion of the treating physician, patients on rituximab SC may be switched back to the IV formulation in the event of significant cutaneous reactions or due to other tolerability issues.

iii. **My patient is currently receiving rituximab (Rituxan). Can my patient stay on the reference biologic (i.e., rituximab (Rituxan))?**

Yes, patients currently on rituximab (Rituxan) or initiated on rituximab (Rituxan) before the PDRP-communicated deadline may continue with the reference biologic until their treatment course has ended.

Patients who are continuing treatment with rituximab (Rituxan) after the PDRP-communicated deadline must have an enrolment form and treatment claim(s) submitted in eClaims prior to that date to be eligible for continued reimbursement of rituximab (Rituxan). **Effective the PDRP-communicated deadline all new patient starts for the indications listed on the March 13, 2020 memo must be on a rituximab biosimilar.**

iv. **My patient is currently receiving rituximab (Rituxan or Rituxan SC). Can my patient be switched to a rituximab biosimilar for the remainder of their treatment cycles?**

At the discretion of the treating physician or based on individual hospital policy, patients currently on rituximab (Rituxan or Rituxan SC) may be switched over to a rituximab biosimilar (IV only) for the remainder of the funded doses if rituximab biosimilars are funded for the specific indication.

If the patient is already enrolled in an NDFP policy for rituximab, please re-enroll the patient in the updated rituximab enrolment form in order to submit treatments for rituximab biosimilar.

NOTE: Existing patients can switch from Rituxan or Rituxan SC to a rituximab biosimilar; however, patients who switch to a rituximab biosimilar will not be funded for further rituximab (Rituxan [IV formulation only]) treatments.

v. **How does rituximab biosimilar funding affect funding for subcutaneous rituximab (Rituxan SC)?**

Subcutaneous rituximab (Rituxan SC) will continue to be funded as an option if it is funded for the specific indication. All new patients initiating treatment on or after the PDRP-communicated deadline must receive the first dose of rituximab biosimilar intravenously before switching to Rituxan SC.

Supporting Documents

None required.

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

- Clinic note documenting treatment history.

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

....
Day Month Year

Form 792