Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

# Rituximab (Biosimilar IV) and Rituximab SC in Combination with Chemotherapy - Indolent B-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 (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, b, c, and d:

a. Patient has follicular lymphoma or other indolent B-cell histology lymphoma (e.g., mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytoid lymphoma (Waldenstrom's macroglobulinemia), hairy cell leukemia, mucosa-associated lymphoid tissue (MALT) lymphoma but excluding diffuse small lymphocytic lymphoma/chronic lymphocytic leukemia) ☐ Yes

b. Patient: ○ is untreated
○ has been previously treated

c. Patient has not received previous treatment with rituximab for indolent B-cell lymphoma ☐ Yes

d. Patient will receive rituximab in combination with chemotherapy ☐ Yes

Please select one of the following regimens:

○ R-CHOP ○ R-CVP ○ R-fludarabine ○ R-FCM
○ R-cladribine ○ R-bendamustine ○ VR-CAP ○ Other

Specify: .....

## 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 ○ 3 ○ 4

c. LDH value before the start of treatment

- Please select one of the following: ○ Elevated ○ Normal

d. Select the number of extranodal sites: ○ 0 ○ 1 ○ >1

e. Select all sites of extranodal disease (select all that apply): ☐ Adrenal ☐ Kidney ☐ Bone marrow ☐ Testicular ☐ Central nervous system ☐ Other

Other (specify): .....

f. Select lymphoma stage ○ I ○ II ○ III ○ IV

## 4. Funded Dose

Rituximab 375 mg/m$^2$ IV (See Note 3) or 1400 mg SC (fixed dose) given with chemotherapy for 4 - 8 cycles

**All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC**

## 5. Notes

1. Patients previously treated with rituximab for **aggressive histology lymphoma** are eligible if the interval from the last dose of rituximab is greater than 1 year. Please provide a copy of pathology report.
2. The IV and SC formulations of rituximab are not interchangeable.
3. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously 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 May 15, 2020, must receive the first dose of rituximab biosimilar intravenously before switching to Rituxan SC.

## 7. Supporting Documents

Pathology reports (current and/or previous diagnosis) if patient has been previously treated with rituximab for aggressive histology lymphoma.

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

..... ..... .....
Day Month Year

*Form 796*