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 (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 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 <u>not</u> 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	○ Acalabrutinib-BR		○ 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 (CNS) ☐ 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.

4. Patients using acalabrutinib-BR for mantle cell lymphoma (MCL) must have a pathological diagnosis of MCL, be ineligible for autologous stem cell transplantation, and must not have a history of CNS lymphoma or leptomeningeal disease. Patients who have already initiated BR will not be eligible to add publicly funded acalabrutinib to the regimen. Please contact the Ministry's Exceptional Access Program for the full funding criteria for acalabrutinib.

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