

Rituximab (Biosimilar IV) - Single Agent - Indolent 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 (m²): * 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:

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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:

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2. Eligibility Criteria

The patient must meet the following criteria

Patient has:

- a. follicular lymphoma and is unable to tolerate further chemotherapy due to hematologic toxicity ☐ Yes
- b. follicular lymphoma and has failed anthracycline or purine analog chemotherapy ☐ Yes
- c. mantle cell lymphoma ☐ Yes
- d. other CD20 positive low grade lymphoma (e.g., 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
- e. post transplant lymphoproliferative disorder ☐ Yes

2c) Mantle cell lymphoma eligibility criteria

- ☐ Is unable to tolerate further chemotherapy
- ☐ Is resistant or refractory to 2 or more lines of chemotherapy
- ☐ Has failed anthracycline or purine analog chemotherapy

2d) Other CD20 positive low grade lymphoma eligibility criteria

- ☐ Is unable to tolerate further chemotherapy
- ☐ Is resistant or refractory to 2 or more lines of chemotherapy
- ☐ Has failed anthracycline or purine analog chemotherapy

3. Baseline Information

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

4. Funded Dose

- Single agent rituximab 375mg/m² weekly for 4 weeks. After treatment with single agent rituximab, patients are eligible for retreatment with single agent rituximab if a durable response lasting a minimum of 6 months is achieved. Patients who have previously received rituximab in combination with chemotherapy and/or rituximab maintenance are not eligible for single agent rituximab retreatment.

5. Intent

☐ Curative
 ☐ Palliative
 ☐ Adjuvant
 ☐ Neoadjuvant

6. FAQs

- i. **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.**

- ii. **My patient is currently receiving rituximab (Rituxan). 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) 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 to a rituximab biosimilar; however, patients who switch to a rituximab biosimilar will not be funded for further rituximab (Rituxan [IV formulation only]) treatments.

7. Supporting Documents

To ensure reimbursement of your claim, both the completed enrolment form and a copy of the required documentation (where applicable) must be submitted through CCO e-Claims.

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

Day Month Year