

# Rituximab (Biosimilar IV) and Rituximab SC - Retreatment - 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 (m<sup>2</sup>): ..... \* 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 and b:

- a. Rituximab will be used in combination with chemotherapy for the treatment of follicular or other indolent lymphoma.  Yes
- b. The patient has previously received rituximab (including combination rituximab-chemotherapy, rituximab monotherapy, or maintenance rituximab) and has sustained a response and remained disease free for at least 6 months following the last dose of rituximab received.  Yes

## 3. Baseline Information

a. Date of pathological diagnosis: \_\_\_\_\_

Day    Month    Year

b. Histology of indolent B-cell lymphoma (please select the most representative histology):

- Follicular       Mantle Cell       Marginal Zone  
 Lymphoplasmacytoid       Other

Specify: .....

c. The patient has previously been treated with rituximab:

- Rituximab in combination with chemotherapy (without maintenance rituximab)  
 Rituximab maintenance therapy (following any type of induction regimen)  
 Rituximab monotherapy (repeated pulses of monotherapy rituximab and no maintenance)

d. Chemotherapy regimen used with prior rituximab induction:

- CVP       CHOP       FCM       FC       Chlorambucil       Cladribine  
 Bendamustine       Fludarabine       Not applicable       Other

Specify: .....

e. Duration of response to prior rituximab-based therapy for indolent lymphoma:

- 6 months - 1 year       1 year - 2 years  
 > 2 years

f. Date of relapse after last dose of initial rituximab-based treatment: \_\_\_\_\_

Day    Month    Year

g. Chemotherapy regimen to be used with rituximab retreatment:

- CVP       CHOP       FCM       FC       Chlorambucil       Cladribine  
 Bendamustine       Fludarabine       Not applicable       Other

Specify: .....

h. Line of therapy for the rituximab retreatment:

- 1<sup>st</sup>       2<sup>nd</sup>       3<sup>rd</sup>       4<sup>th</sup>  
 5<sup>th</sup>       Other

Specify: .....

(Note: For patients who have received multiple treatments of rituximab monotherapy, please count each pulse dose of monotherapy rituximab as a line of therapy.)

- i. Screening for Hepatitis B virus with HBsAg and HBcAb has been completed or is in progress       Yes       No
- j. ECOG Performance Status at the time of enrolment:       0       1       2       3  
 4
- k. LDH value before the start of treatment:
- Please select one of the following:       Elevated       Normal
- l. Select the number of extranodal sites:       0       1       >1
- m. Select all sites of extranodal disease (select all that apply):
- Adrenal       Kidney
  - Bone marrow       Testicular
  - Central nervous system
  - Other
- Other (specify): .....
- n. Select lymphoma stage:       I       II       III       IV

#### 4. Funded Dose

Rituximab 375 mg/m<sup>2</sup> IV (See Note 4) or 1400 mg SC (fixed dose) in combination with chemotherapy, up to a maximum of 8 cycles.

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

#### 5. Notes

1. NDFP funding of rituximab retreatment does not apply to:
  - a. Indolent lymphoma patients who have remained treatment free for less than 6 months following the last rituximab dose used in the treatment of indolent lymphoma.
  - b. Patients with chronic lymphocytic leukemia/small lymphocytic lymphoma.
2. NDFP funding does not extend to use of maintenance rituximab after rituximab retreatment.
3. The IV and SC formulations of rituximab are not interchangeable.
4. 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 previously tolerated rituximab SC (with chemotherapy and/or maintenance), does the first dose of retreatment need to be given as IV?**

After an extended duration without rituximab exposure, treating physicians should consider giving the first treatment of rituximab retreatment intravenously. If the patient tolerates the first dose IV, then subsequent doses may be given as SC.

**iii. 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.

**iv. 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.**

**v. 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.

**vi. 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.

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## **7. Supporting Documents**

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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): .....

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Day    Month    Year