Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Rituximab (Biosimilar IV) and Rituximab SC - Retreatment - Aggressive Histology 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 the following criteria:

Rituximab retreatment in combination with salvage chemotherapy for relapsed aggressive histology CD20+ lymphoma with intent to proceed to autologous stem cell transplantation. ☐ Yes

- To be used with salvage chemotherapy (e.g., DHAP (dexamethasone, cytarabine, cisplatin), GDP (gemcitabine, dexamethasone, cisplatin))
- The patient was previously treated with rituximab-based chemoimmunotherapy (e.g., R-CHOP) for aggressive histology lymphoma and had a best response of at least partial response (PR)

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. Patient's response to prior rituximab-based therapy ○ Complete response ○ Partial response

d. Salvage chemotherapy regimen to be used with rituximab retreatment ○ GDP ○ DHAP ○ Other (Specify)

Other (specify): .....

4. Funded Dose

Rituximab 375mg/m^2 intravenously (IV) or rituximab 1400 mg subcutaneously (SC) as a fixed dose on day 1 of each cycle of salvage chemotherapy for up to 3 cycles.

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

5. Notes

1. The IV and SC formulations of rituximab are not interchangeable.
2. 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.
3. For IV administration, only rituximab (Biosimilar IV) is funded for this indication.

6. FAQs

i. ***My patient is currently receiving rituximab (in combination salvage chemotherapy) through non-publicly funded means for relapsed aggressive histology lymphoma. Can my patient be transitioned over to receive funding for rituximab through the New Drug Funding Program (NDFP)?***

Provided the funding criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage of a rituximab IV biosimilar or rituximab SC through NDFP. Funding is for up to 3 cycles of rituximab (in combination with salvage chemotherapy), regardless of funding source.

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. Please note that for this indication, only the rituximab biosimilar will be funded for IV administration.

7. Supporting Documents

None required at time of enrolment.

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

- Clinic notes documenting diagnosis, previous treatment history, and previous treatment response.

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

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Day Month Year

Form 849