Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Rituximab (Biosimilar IV) and Rituximab SC - In Combination with Venetoclax - Relapsed Chronic Lymphocytic Leukemia

(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 is used in combination with venetoclax for the treatment of adult patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy, irrespective of their 17p deletion status. ☐ Yes

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Prior B-cell receptor pathway inhibitors (ibrutinib or idelalisib), if applicable ○ Ibrutinib ○ Idelalisib ○ None

c. Chromosome 17p deletion status ○ Absent ○ Present ○ Unknown

4. Funded Dose

After completion of the dose ramp-up period for venetoclax, rituximab is initiated on an every 28-day schedule for a total of six cycles while daily venetoclax continues.

Cycle 1 – rituximab 375 mg/m^2 intravenously (IV), in combination with venetoclax (See Note 3).

Cycles 2 through 6 – rituximab 500 mg/m^2 IV or 1600 mg subcutaneously (SC) as a fixed dose, in combination with venetoclax.

Treatment with venetoclax monotherapy should be continued until disease progression or unacceptable toxicity, up to a maximum of two years from the start of rituximab therapy, whichever comes first [ST-QBP regimen code: VENE+RITU].

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

5. Notes

1. For patients with a high tumour load, consider a slower infusion rate or split the dose of rituximab over 2 days during the first cycle.
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 SC if the patient tolerated the first IV dose.
4. Venetoclax is not funded by Ontario Health (Cancer Care Ontario). For patients who are eligible for Ontario Drug Benefit (ODB) funding, refer to the Ministry of Health's Exceptional Access Program for details.
5. Patients previously treated with an anti-CD20-containing therapy (rituximab or obinutuzumab) and who had a treatment-free interval of 12 months or longer since the last dose of anti-CD20 therapy may be treated with venetoclax and rituximab for relapsed CLL.
6. Retreatment with venetoclax, either in combination with rituximab or as monotherapy, may be funded for patients who did not experience disease progression during treatment or within 12 months of completing treatment with obinutuzumab with venetoclax.

6. FAQs

i. ***My patient is currently receiving rituximab (in combination with venetoclax) through non-publicly funded means for relapsed CLL. 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 a total of 6 cycles of rituximab (in combination with venetoclax), regardless of funding source. As of the implementation date, patients currently on non-publicly funded rituximab (Rituxan IV) or rituximab SC (in combination with venetoclax for relapsed CLL) may transition to a publicly funded rituximab biosimilar IV or rituximab SC.

ii. ***How can my patient access venetoclax as part of this regimen?***

Refer to the Ministry of Health's Exceptional Access Program for more details. Note that patients must be eligible to receive benefits under the ODB program in order to apply for venetoclax coverage under the Exceptional Access Program.

iii. ***My patient is currently on venetoclax with a plan to start them on combination therapy with rituximab. When do I start the rituximab portion?***

The rituximab portion may be started after the patient has completed the ramp-up period with venetoclax and has received the 400 mg dose for 7 days. Please refer to the Health Canada Product Monograph for the venetoclax dosing schedule during the ramp-up phase.

iv. ***How long are patients continued on venetoclax after the rituximab cycles have been completed?***

As per the Health Canada Product Monograph, treatment with venetoclax should continue for 24 months from cycle 1, day 1 of rituximab.

v. ***My patient is currently receiving and responding to venetoclax monotherapy but has not achieved an adequate response. Will the addition of rituximab be funded for my patient?***

Yes, existing patients on venetoclax will be eligible for the addition of rituximab provided funding criteria are met, and the patient's disease is not progressing or has not progressed on venetoclax. The funded duration of venetoclax therapy from the point of rituximab addition will be up to a maximum of two years.

To be eligible for funding, new patients being considered for therapy with venetoclax and rituximab must be able to receive both drugs concurrently after the ramp-up period of venetoclax has been completed.

vi. ***My patient previously responded to treatment with venetoclax and rituximab for their relapsed CLL and I would like consider use of the same regimen. Would re-treatment be eligible for funding?***

Yes, rituximab funding as part of re-treatment in combination with venetoclax, within the same line of therapy, may be considered through NDFP for patients who responded to and completed 24 months of therapy with a progression-free interval of at least 12 months. Sites should submit a new enrolment form as a Prior Approval in eClaims (along with the most recent clinic note) for re-treatment consideration.

vii. ***My patient is currently being treated with ibrutinib for 2nd line CLL. Upon disease progression, will they be eligible for public funding of venetoclax in combination with rituximab as a next line of therapy?***

Patients with relapsed/refractory CLL who have disease progression on or are intolerant to B-cell receptor pathway inhibitors will be eligible for venetoclax and rituximab as their next line of therapy. Conversely, patients on venetoclax and rituximab as a 2nd line option will be eligible for ibrutinib (or idelalisib with rituximab) as a next publicly funded line of therapy for reasons of either intolerance or disease progression, provided patients have not received prior treatment with either option and all other funding criteria are met.

7. Supporting Documents

None required at time of enrolment.

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

- A clinic note detailing the patient's treatment history including response to prior therapy for CLL.

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

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Day Month Year