Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Rituximab (Biosimilar IV) - In Combination with Idelalisib - 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)

.....

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 idelalisib for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL). ☐ Yes

3. Baseline Information

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

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

c. Rituximab-idelalisib is used as ___ line treatment ○ 2nd ○ 3rd ○ >3rd

d. Prior systemic treatments received (select all that apply)

☐ Obinutuzumab
☐ Rituximab
☐ Bendamustine
☐ Chlorambucil
☐ Cyclophosphamide
☐ Fludarabine
☐ Ibrutinib
☐ Other

Other (specify): .....

e. The patient has initially been treated with ibrutinib for relapsed CLL but has experienced intolerance and needs to be switched to rituximab-idelalisib ☐ Yes

4. Funded Dose

Rituximab 375mg/m^2 Day 1, Week 1, then 500mg/m^2 Day 1 on weeks 3, 5, 7, 9, 13, 17, and 21. The number of cycles funded equals 8.

5. Notes

1. Rituximab-idelalisib is not funded as a sequential treatment option for patients whose disease has progressed on ibrutinib in the relapsed setting (and vice versa).
2. Patients who have experienced intolerance but not disease progression to ibrutinib in the relapsed setting may switch to rituximab-idelalisib (and vice versa). Documentation on the nature of the intolerance is required.
3. Rituximab is only funded if used in combination with idelalisib.
4. For patients with a high tumour load, consider a slower infusion rate or split dosing over 2 days during the first cycle.
5. The recommended dose of idelalisib is 150mg twice daily. The product monograph for idelalisib notes that idelalisib is contraindicated in first line CLL outside of a clinical trial.
6. Idelalisib is not funded by CCO. For patients who are eligible for Ontario Drug Benefit funding, refer to the Ministry's Exceptional Access Program for details.
7. Other rituximab-based regimens for relapsed CLL may be funded for patients with a progression-free interval of at least 6 months after prior CD20-targeting therapy.

6. FAQs

i. **My patient is currently receiving rituximab (in combination with idelalisib) through private means. Can my patient be transitioned over to receive funding 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 rituximab through the New Drug Funding Program. Please note that coverage will be for the remaining cycles to complete the course of treatment. For example, a patient who has received 4 cycles through private means is only eligible for funding of up to an additional 4 cycles.

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

Refer to the Ministry's Exceptional Access Program for more details. Note that patients must be eligible for Ontario Drug Benefits in order to access publicly funded idelalisib.

iii. **My patient has previously been treated with 1st line rituximab-fludarabine for CLL. Is my patient eligible to receive rituximab-idelalisib?**

The pivotal trial for rituximab-idelalisib included patients who had been treated with prior anti-CD20 antibody-based regimens. Hence, your patient would be eligible to receive rituximab-idelalisib in the relapsed setting, provided that funding criteria are met.

iv. **I would have liked my patient to have access to both rituximab-idelalisib and ibrutinib for relapsed CLL. Why is the sequential treatment of ibrutinib (after disease progression on rituximab-idelalisib) not funded? Consequently, why is the sequential treatment of rituximab-idelalisib (after disease progression on ibrutinib) also not funded?**

In the absence of direct evidence, pCODR was unable to make an informed recommendation on the sequencing of rituximab-idelalisib and ibrutinib in relapsed CLL.

Although sequential treatment after disease progression in relapsed CLL is not funded, switching from ibrutinib to rituximab-idelalisib (and vice versa) due to intolerance would be funded. A clinic note documenting the nature of the intolerance and confirmation that the disease had not progressed on ibrutinib in the relapsed setting must be provided at the time of the request.

v. **My patient has a high tumour load. Can I split the rituximab dose over 2 days?**

It is noted that for patients with very high tumour load, a clinical decision may be made to split the rituximab dose over a 2 day period in the first cycle. CCO will fund the rituximab dose provided the total dose does not exceed the stated funded dose.

vi. **If my patient has excessive toxicity or is intolerant to idelalisib, will rituximab be funded as a single agent?**

To be eligible for funding, patients must be able to start rituximab in combination with idelalisib. According to pCODR's Clinical Guidance Panel, there is "data that suggest efficacy is quite limited in CLL when rituximab is used alone." CCO's Hematology Drug Advisory Committee also does not support rituximab monotherapy.

vii. **My patient had experienced a severe reaction from rituximab in the past. Will idelalisib be funded as a single agent?**

To be eligible for funding, patients must be able to start rituximab in combination with idelalisib.

viii. **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.**

ix. **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

None required for this policy.

In the absence of collecting supporting documentation at the time of enrolment:

- CCO reserves the right to perform an audit of patient eligibility.
- In the event of an audit, CCO may request the following:
    - A clinic note and treatment history confirming that the patient's disease has not progressed on or after ibrutinib treatment in the relapsed setting.
    - Confirmation that rituximab is given in combination with idelalisib.
- For patients on ibrutinib who require to be switched to rituximab-idelalisib due to intolerance:
    - A clinic note documenting the nature of the ibrutinib intolerance and confirming that the disease has not yet progressed on ibrutinib in the relapsed setting.

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

....
Day Month Year

Form 930