Ontario Health / Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Rituximab (Biosimilar IV) and Rituximab SC - In Combination with Ibrutinib for Previously Treated Waldenstroms Macroglobulinemia

(This form should 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

Specify Trial:
○ Clinical Trial 1 ○ Clinical Trial 2
○ Clinical Trial 3 ○ Other

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

Rituximab will be used in combination with ibrutinib for the treatment of adult patients with relapsed or refractory Waldenstrom's Macroglobulinemia (WM). ☐ Yes

Patients must have:

- Received at least 1 prior line of therapy; AND,
- Meet at least 1 criterion for treatment according to the International Workshop on Waldenstrom's Macroglobulinemia (IWWM) consensus panel criteria; AND,
- Have a good performance status.

Patients must not have:

- Been previously treated and had a poor response or progression on a BTK inhibitor;
- Disease transformation.

3. Baseline Information

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

b. Is the patient transitioning from a private payer? ○ Yes ○ No

c. If yes, how many doses of rituximab did the patient receive prior to the transition? ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7

d. If yes, please indicate the date of the last administered dose. _____ Day _____ Month _____ Year

4. Funded Dose

Rituximab 375 mg/m^2 intravenously (IV) or 1400 mg subcutaneously (SC) (fixed dose) once weekly on weeks 1-4 and 17-20, in combination with ibrutinib.

Treatment should continue until disease progression or unacceptable toxicity up to a maximum of 8 doses, whichever comes first.

[ST-QBP regimen code: IBRU+RITU]

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

5. Notes

1. Completion of this form is for rituximab funding only. Public funding for ibrutinib must be obtained through a Ministry of Health program. Please check that your patient will be eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration into the Trillium Drug Program.

2. If ibrutinib is stopped due to intolerable toxicity, rituximab must also be stopped.

3. Retreatment with rituximab and ibrutinib is not funded.

6. FAQs

1. **My patient is currently receiving rituximab through non-publicly funded means (e.g., private insurance). Can my patient be transitioned to receive funding through the New Drug Funding Program (NDFP)?**

   Provided the eligibility 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 through the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

   Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:

   - A clinic note, relevant lab values, and imaging (if applicable) from treatment initiation, and
   - Pathology report(s) demonstrating Waldenstrom's Macroglobulinemia, and
   - The most recent clinic note, lab values, and imaging (if applicable).

Supporting Documents

None required at time of enrolment.

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

- Clinic notes outlining patient and treatment history/response, and
- Pathology report(s) demonstrating Waldenstrom's Macroglobulinemia, and
- Lab values and imaging (if applicable) demonstrating no disease progression.

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

....
Day Month Year

Form 1092