Bendamustine - First Line - Indolent Non-Hodgkin Lymphoma and Mantle Cell Lymphoma

(This form should be completed before the first dose is dispensed.)

Version History

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

Bendamustine is used in combination with rituximab in the first line setting in patients with indolent CD20 positive non-Hodgkin lymphoma or mantle cell lymphoma. ☐ Yes

Patients with mantle cell lymphoma may use bendamustine in combination with rituximab and acalabrutinib.

The patient has an ECOG performance status of less than or equal to 2.

3. Baseline Information

a. Patient's diagnosis

- ○ Mantle cell lymphoma
- ○ Other indolent non -Hodgkin's lymphoma

b. If the patient has mantle cell lymphoma, please select the regimen that will be used

- ○ BR
- ○ BR with acalabrutinib

4. Funded Dose

Bendamustine 90mg/m^2 on Days 1 and 2 of a 28-day cycle to a maximum of 6 cycles (combination therapy).

5. Notes

1. Bendamustine is not funded if used as a single agent.

2. Patients who receive first line rituximab bendamustine would be eligible for rituximab maintenance provided that the maintenance rituximab funding criteria are met.

3. Patients using acalabrutinib-BR for mantle cell lymphoma (MCL) must have a pathological diagnosis of MCL, be ineligible for autologous stem cell transplantation, and must not have a history of CNS lymphoma or leptomeningeal disease. Patients who have already initiated BR will not be eligible to add publicly funded acalabrutinib to the regimen. Please contact the Ministry's Exceptional Access Program for the full funding criteria for acalabrutinib.

4. Completion of this form is for bendamustine funding only. For mantle cell lymphoma patients, funding for acalabrutinib must be obtained through the Ministry's Exceptional Access 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.

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:

- Pathology report confirming indolent lymphoma diagnosis (mantle cell lymphoma if using acalabrutinib with BR)
- Clinic notes outlining patient and treatment history/response.
- CT scans demonstrating no disease progression.

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

....
Day Month Year