Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Polatuzumab Vedotin with Bendamustine and Rituximab (Biosimilar) - Relapsed or Refractory Diffuse Large B-cell Lymphoma

(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

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

Polatuzumab vedotin is used in combination with bendamustine and rituximab (pola-BR) for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, who are not eligible for autologous stem cell transplant (ASCT) and have received at least 1 prior therapy. ☐ Yes

Eligible patients should have good performance status and a life expectancy greater than or equal to 24 weeks.

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

c. Is polatuzumab vedotin in combination with bendamustine and rituximab being used as a bridge to CAR T-cell therapy? ○ Yes ○ No

d. Is the patient transitioning from a private pay or compassionate program? ○ Yes ○ No

e. If yes, how many cycles did the patient have prior to the transition?
○ 1 ○ 2 ○ 3 ○ 4 ○ 5

4. Funded Dose

Cycle 1:
Rituximab 375mg/m^2 intravenously (IV) on Day 1,
Polatuzumab vedotin 1.8mg/kg IV on Day 2,
Bendamustine 90mg/m^2 IV on Days 2 and 3

Cycles 2 to 6:
Rituximab 375mg/m^2 IV on Day 1,
Polatuzumab vedotin 1.8mg/kg IV on Day 1,
Bendamustine 90mg/m^2 IV on Days 1 and 2

Treatment with pola-BR should continue for a maximum of 6 cycles (21 days per cycle), or until unacceptable toxicity or disease progression, whichever occurs first.

[ST-QBP regimen code: BEND+POLA+RITU]

5. Notes

1. NDFP will only fund polatuzumab vedotin in combination with bendamustine and rituximab (pola-BR). An exception is if pola-BR is being used as a bridge to CAR T-cell therapy, in which case bendamustine may be omitted if appropriate based on clinician judgement.
2. Enrolment in this policy will fulfill enrolment requirements for all drugs in this regimen (polatuzumab vedotin, rituximab biosimilar, and bendamustine)
3. Pola-BR is not funded:
    a. In patients with previously untreated diffuse large B-cell lymphoma (DLBCL); or
    b. In patients with active CNS lymphoma; or
    c. If used as salvage therapy for patients who are eligible for ASCT; or
    d. In patients with Burkitt lymphoma
4. Pola-BR may be considered in patients with transformed follicular lymphoma to DLBCL, HIV-related lymphoma, grey zone lymphoma, and mediastinal large B-cell lymphoma.
5. Pola-BR may be considered in patients who have progressed on prior CAR -T-cell therapy provided the patient is not eligible for ASCT.

6. FAQs

i. **My patient is currently receiving pola-BR through non-publicly funded means for relapsed or refractory diffuse large B-cell lymphoma. 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 pola-BR through NDFP. Please submit as a prior approval request with clinic notes that document the patient's clinical and treatment history, including confirmation that the patient is not eligible for autologous stem-cell transplant.

Funding for pola-BR is for up to 6 cycles, regardless of the funding source.

ii. **If my patient is not able to tolerate rituximab, will NDFP fund polatuzumab vedotin in combination with bendamustine when used with non-publicly funded obinutuzumab?**

NDFP will only fund polatuzumab vedotin in combination with bendamustine and rituximab. An exception is if pola-BR is being used as a bridge to CAR T-cell therapy, in which case bendamustine may be omitted if appropriate based on clinician judgement.

iii. **My patient is currently on another regimen for relapsed or refractory diffuse large B-cell lymphoma. Will NDFP fund a switch to pola-BR?**

The decision to switch should be based on a discussion between the treating physician and patient. Provided all other funding criteria are met, NDFP can accommodate a switch to pola-BR for patients currently receiving alternate therapies but whose disease has not progressed, as well as patients who have just initiated therapy. Please submit as a prior approval request including the most recent clinic note (and response to therapy, if able to assess).

Supporting Documents

None required at time of enrolment.

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

- Clinic note indicating the patient’s clinical and treatment history, including confirmation that the patient is not eligible for ASCT.

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

....
Day Month Year

Form 931