



Polatuzumab Vedotin with Rituximab (Biosimilar IV and Rituximab SC) - In Combination with Chemotherapy for Previously Untreated LBCL

(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 (m²): * 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:

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b. Intended regimen schedule:

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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 and rituximab will be used in combination with cyclophosphamide, doxorubicin and prednisone (CHP) for the treatment of adult patients with previously untreated CD20-positive large B-cell lymphoma (LBCL) that is classified as activated B-cell-like (ABC) subtype.

Yes

Patients must have:

- Diffuse Large B-Cell Lymphoma not otherwise specified (DLBCL NOS), high-grade B-cell lymphoma, Epstein Barr Virus (EBV)-positive DLBCL NOS, or T-cell/histiocyte-rich LBCL
- International Prognostic Index (IPI) score of 2 to 5
- A good performance status

Patients must not have:

- Follicular lymphoma grade 3B
- Germinal center B-cell type (GCB) or indeterminate LBCL

3. Baseline Information

- a. ECOG Performance Status at the time of enrolment 0 1 2
- b. IPI Score 2 3 4 5
- c. Is the patient transitioning from a private payer? Yes No
- d. If yes, how many cycles of polatuzumab and rituximab did the patient receive prior to the transition? N/A 1 2 3
 4 5
- e. If yes, please indicate the date of the last administered dose
- Day Month Year

4. Funded Dose

Rituximab 375 mg/m² intravenously (IV) or 1400 mg fixed dose subcutaneously (SC), and polatuzumab vedotin 1.8 mg/kg IV on Day 1, with CHP.

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

Treatment with polatuzumab-rituximab-CHP (pola-R-CHP) should continue for a maximum of 6 cycles, or until unacceptable toxicity or disease progression, whichever comes first.

1 cycle = 21 days

[ST-QBP regimen code(s): CHP+POLA+RITU]

5. Notes

1. Completion of this form will enroll the patient in both polatuzumab and rituximab.
2. Due to long administration times, rituximab and polatuzumab may be given on sequential days for cycle 1.
3. Patients previously treated for indolent lymphoma and whose disease has transformed into a confirmed ABC subtype of LBCL may be eligible, provided all other eligibility criteria are met.
4. The IV and SC formulations of rituximab are not interchangeable.
5. Patients with a contraindication to doxorubicin (e.g., low cardiac ejection fraction; cumulative lifetime anthracycline dose reached) may use etoposide as a funded alternative. A prior approval is not required unless there is clinical uncertainty.
6. Patients will be eligible for pola-BR as a subsequent line of therapy if they have either of the following:
 - A disease-free interval of 6 months or more AND are using pola-BR as a bridge to CAR T-cell therapy; or,
 - A disease-free interval of 12 months or more after completion of pola-R-CHP.

6. FAQs

1. My patient is currently receiving polatuzumab and/or 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 and imaging (if applicable) from treatment initiation, and
- The most recent clinic note and imaging (if applicable), and
- Pathology report demonstrating ABC subtype of LBCL by a validated test.

The NDFP will fund a total duration of 6 cycles, regardless of funding source.

3. My patient is experiencing severe neuropathy from polatuzumab. Can they continue with rituximab and CHP?

Yes, rituximab with chemotherapy may be continued if polatuzumab is held or stopped for toxicity.

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.
- Pathology report demonstrating ABC subtype of LBCL by a validated test.
- CT scans demonstrating no disease progression.

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

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Day Month Year