Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Rituximab (Biosimilar IV) - As Part of the MATRix Regimen in Newly Diagnosed, Previously Untreated Primary Central Nervous System Lymphoma

(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)

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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:

.....

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 high-dose methotrexate, cytarabine and thiotepa (MATRix regimen) as induction therapy in patients with newly diagnosed, previously untreated primary central nervous system (CNS) lymphoma. ☐ Yes

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 ○ 3

c. If known to be seropositive for HIV, the patient's HIV status is adequately controlled. ○ Yes ○ Not applicable

4. Funded Dose

Rituximab 375 mg/m^2 intravenously on Day -5 and Day 0 of the MATRix regimen for up to 4 cycles.

Rituximab is funded when used in combination with high-dose methotrexate, cytarabine and thiotepa (ST-QBP regimen code: MATRIX).

5. Notes

1. Patients previously treated with rituximab for indolent or aggressive histology lymphoma are eligible if the patient has sustained a response and remained disease free for at least 6 months following the last dose of rituximab received. Please provide a copy of pathology report.

2. For funding of thiotepa, a separate enrolment form must be submitted. Please refer to the High-Cost Therapy Funding Program (HCTFP) policy entitled 'Thiotepa (Inpatient) - As Part of the MATRix Regimen in Newly Diagnosed, Previously Untreated Primary Central Nervous System Lymphoma'.

6. FAQs

i. **My patient tolerated their initial dose of rituximab intravenously as part of this regimen. Are they eligible to be switched over to the subcutaneous formulation for the remainder of their treatment cycles?**

When this drug and indication were reviewed for public funding consideration, the available literature only supported use of the intravenous formulation. Rituximab will only be funded if given intravenously at the dose and schedule specified in the Funded Dose section of the enrolment form.

ii. **If my patient has toxicity to one of the chemotherapy agents, can I drop that drug while continuing the other drug(s) with rituximab?**

Rituximab is not funded if your patient is unable to receive high-dose methotrexate, cytarabine and thiotepa at the time of rituximab initiation. If your patient is initially treated on the full MATRix regimen, they will be eligible for continued NDFP funding of the rituximab portion, when used with chemotherapy, in cases of toxicity or intolerance to one or more agents in the MATRix regimen.

iii. **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.**

iv. **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

Pathology reports (current and/or previous diagnosis) if patient has been previously treated with rituximab for indolent or aggressive histology (non-primary CNS) lymphoma.

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

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Day Month Year