Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Obinutuzumab – In Combination with Chemotherapy for Refractory Follicular 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
  ○ 1-Unknown primary (submit pathology report and clinic note)

scenario:

- 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

The patient must meet the following criteria:

- Obinutuzumab, in combination with chemotherapy, is used in adults with follicular lymphoma whose disease is **refractory to a rituximab containing regimen** and has a good performance status. ☐ Yes

Rituximab refractory disease is defined as having no response to or progression during or within 6 months after treatment with rituximab or a rituximab-containing regimen.

Patients with non-follicular indolent lymphoma histologies (excluding chronic lymphocytic leukemia (CLL) and mantle cell lymphoma) may be eligible for obinutuzumab funding provided all other funding criteria are met.

3. Baseline Information

Complete the following:

a. Select patient's ECOG performance status at the time of enrolment: ○ 0 ○ 1 ○ 2

b. Select patient's histology:

○ Follicular ○ Marginal Zone
○ Lymphoplasmacytic Lymphoma (Waldenstrom's Macroglobulinemia)
○ Small Lymphocytic Lymphoma

c. Select the chemotherapy regimen to be used with obinutuzumab:

○ Bendamustine ○ CHOP ○ CVP ○ Fludarabine-based regimen
○ Chlorambucil ○ Other (please specify)

Other (specify): .....

d. Screening for Hepatitis B virus with HBsAg and HBcAb has been completed or is in progress: ○ Yes ○ No

4. Funded Dose

Cycle 1: Obinutuzumab 1000 mg intravenously days 1, 8, 15.
Cycles 2 to 6: Obinutuzumab 1000 mg intravenously day 1 only.

Obinutuzumab is only funded when used in combination with chemotherapy.

5. Notes

1. Patients being treated with bendamustine in combination with obinutuzumab must complete a separate enrolment form for bendamustine (eClaims form title: Bendamustine - Relapsed/Refractory - Indolent Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma).

6. FAQs

i. **My patient is currently receiving obinutuzumab through private or compassionate means. 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 obinutuzumab through NDFP for the remaining cycles of induction and/or maintenance therapy.

ii. **My patient is unable to tolerate the chemotherapy backbone. Can I drop the chemotherapy and continue obinutuzumab?**
Single agent obinutuzumab induction is not funded. If the patient is not able to tolerate the current chemotherapy regimen, switches to alternate regimens may be considered through Prior Approval at treatment level.

iii. **My patient is currently on chemotherapy prior to obinutuzumab funding. Can I add obinutuzumab to the treatment regimen?**
Provided patients meet obinutuzumab funding criteria, patients currently on chemotherapy may add obinutuzumab to the chemotherapy regimen. Requests to add obinutuzumab to the remaining cycles of chemotherapy may be considered as a Prior Approval request.

iv. **My patient has completed obinutuzumab induction and/or maintenance and has sustained a durable response. Can I re-treat with rituximab or obinutuzumab upon relapse?**
Patients who are treated with obinutuzumab for relapsed/refractory follicular lymphoma are not eligible for rituximab or obinutuzumab re-treatment once the treatment course is completed.

6. Supporting Documents

None required at the time of enrolment.

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

- Pathology report indicating indolent lymphoma histology
- Clinic notes indicating treatment history

To ensure reimbursement of your claim, both the completed enrolment form and a copy of the required documentation (where applicable) must be submitted through CCO e-Claims.

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

26 (Day) 10 (Month) 2018 (Year)