Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Obinutuzumab - in Combination with Venetoclax for Previously Untreated Chronic Lymphocytic Leukemia

(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

Specify Trial:
○ Clinical Trial 1 ○ Clinical Trial 2
○ Clinical Trial 3 ○ Other

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

The patient must meet the following criteria:

Obinutuzumab is used in combination with venetoclax for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) who are ineligible for fludarabine-based regimens, require treatment, and have good performance status. ☐ Yes

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

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

c. If yes,please indicate the number of cycles of obinutuzumab given (in combination with venetoclax) through non-publicly funded means:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5

4. Funded Dose

Cycle 1: 100 mg Intravenously (IV) on day 1 followed by 900 mg IV on day 2 (or 1000 mg IV on day 1), followed by 1000 mg IV on days 8 and 15, in combination with venetoclax.

Cycles 2 through 6: 1000 mg IV on day 1, in combination with venetoclax.

Treatment should be given for a total of 12 months as a finite treatment (i.e., six 28-day cycles of obinutuzumab in combination with venetoclax, followed by six months of single agent venetoclax).

ST-QBP regimen code: [VENE+OBIN]

5. Notes

1. Please refer to the Ontario Drug Benefit (ODB) Exceptional Access Program (EAP) for full funding criteria of venetoclax used in combination with obinutuzumab.
2. Patients with small lymphocytic lymphoma (SLL) who otherwise meet funding criteria may be considered for obinutuzumab funding under this policy.
3. Patients who complete treatment with obinutuzumab in combination with venetoclax will not be eligible for retreatment with the same regimen upon disease progression.
4. Retreatment with venetoclax, either in combination with rituximab or as monotherapy, may be funded for patients who did not experience disease progression during treatment or within 12 months of completing treatment with obinutuzumab with venetoclax.
5. Other rituximab-based regimens for relapsed CLL may be funded for patients with a progression-free interval of at least 6 months after prior CD20-targeting therapy.
6. Patients with central nervous system (CNS) lymphoma, CNS leukemia, known prolymphocytic leukemia, or history of (or currently suspected) Richter syndrome are not eligible for obinutuzumab in combination with venetoclax.
7. Patients who require a treatment interruption prior to completing 6 cycles of obinutuzumab may resume treatment to complete 6 cycles provided there has been no disease progression during the treatment interruption and no systemic therapy for CLL is given during that time.

6. FAQs

i. **My patient is currently receiving obinutuzumab (in combination with venetoclax) through non-publicly funded means for previously untreated CLL. 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. Please submit as a prior approval request with clinic notes that document the patient's clinical and treatment history including response to therapy if able to assess.

Funding for obinutuzumab is for up to 6 cycles, regardless of the funding source.

ii. **My patient is currently on an alternate treatment regimen for previously untreated CLL. Can I switch them to obinutuzumab in combination with venetoclax?**

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 obinutuzumab in combination with venetoclax for patients currently receiving alternate therapies and whose disease has not progressed. Please submit as a prior approval request including the most recent clinic note (and response to therapy, if able to assess).

iii. **My patient has relapsed after completing six 28-day cycles of obinutuzumab in combination with venetoclax, followed by 6 months of venetoclax monotherapy. Can I treat them with rituximab in combination with venetoclax for relapsed CLL?**

Provided all funding criteria are met, patients who have at least a 12-month disease-free interval after completing treatment with obinutuzumab in combination with venetoclax (followed by venetoclax monotherapy) may be treated with venetoclax in combination with rituximab for relapsed CLL.

iv. **My patient has relapsed after completing six 28-day cycles of obinutuzumab in combination with venetoclax, followed by 6 months of venetoclax monotherapy. Can I treat them with idelalisib in combination with rituximab?**

Provided all funding criteria are met, patients who have a progression-free interval of at least 6 months after prior CD20-targeting therapy may be funded for idelalisib in combination with rituximab.

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 confirming CD20-positive CLL/SLL diagnosis
- Clinic note documenting treatment history

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

....
Day Month Year