

Obinutuzumab - Previously Untreated Chronic Lymphocytic Leukemia

(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 (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:

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:

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2. Eligibility Criteria

a. The patient must meet all of the following criteria:

- Patient has previously untreated chronic lymphocytic leukemia (CLL)
- Patient has adequate renal function
- Fludarabine-based treatment is considered inappropriate for this patient
- Obinutuzumab will be used in combination with chlorambucil

Yes

3. Baseline Information

Complete the following:

a. Select patient's ECOG status at the time of enrolment

0 1 2 3 4

b. Screening for Hepatitis B virus with HBsAg and HBcAb has been completed or is in progress

Yes No

4. Funded Dose

Cycle 1: 100 mg intravenously on day 1, 900 mg intravenously on day 2, 1000 mg intravenously on days 8 and 15.

Cycles 2 to 6: 1000 mg intravenously on day 1 only.

Cycles are 28 days.

Obinutuzumab will be used in combination with chlorambucil.

5. Notes

1. On a time limited basis (6 months), patients who initiated chlorambucil for previously untreated CLL in the three months prior to July 17, 2015 and whose disease has not progressed will have the option of adding obinutuzumab. **Please note that this time-limited funding has ended as of January 17, 2016.**
2. To be eligible for funding, patients must be able to start obinutuzumab in combination with chlorambucil. During the course of treatment, chlorambucil may be temporarily held due to toxicity or intolerance.

6. Supporting Documents

None required at the time of enrolment.

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

- Clinic note(s) outlining that the patient is previously untreated for CLL and that fludarabine-based treatment is considered inappropriate.

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

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Day Month Year