HOSPITAL MEDICINES LIST
RESTRICTIONS CHECKLIST

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Obinutuzumab

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has progressive Binet stage A, B or C CD20+ chronic lymphocytic leukaemia requiring treatment

and

- ○ The patient is obinutuzumab treatment naive

and

- ○ The patient is not eligible for full dose FCR due to comorbidities with a score > 6 on the Cumulative Illness Rating Scale (CIRS) or reduced renal function (creatinine clearance < 70mL/min)

and

- ○ Patient has adequate neutrophil and platelet counts* unless the cytopenias are a consequence of marrow infiltration by CLL

and

- ○ Patient has good performance status

and

- ○ Obinutuzumab to be administered at a maximum cumulative dose of 8,000 mg and in combination with chlorambucil for a maximum of 6 cycles

Note: Chronic lymphocytic leukaemia includes small lymphocytic lymphoma. Comorbidity refers only to illness/impairment other than CLL induced illness/impairment in the patient. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with obinutuzumab is expected to improve symptoms and improve ECOG score to < 2.
* greater than or equal to 1.5×10^9/L and platelets greater than or equal to 75×10^9/L

INITIATION – follicular / marginal zone lymphoma
Re-assessment required after 9 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has follicular lymphoma

or

- ○ Patient has marginal zone lymphoma

and

- ○ Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen*

and

- ○ Patient has an ECOG performance status of 0-2

and

- ○ Patient has been previously treated with no more than four chemotherapy regimens

and

- ○ Obinutuzumab to be administered at a maximum dose of 1000 mg for a maximum of 6 cycles in combination with chemotherapy*

Note: * includes unapproved indications

CONTINUATION – follicular / marginal zone lymphoma
Re-assessment required after 24 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has no evidence of disease progression following obinutuzumab induction therapy

and

- ○ Obinutuzumab to be administered at a maximum of 1000 mg every 2 months for a maximum of 2 years

and

- ○ Obinutuzumab to be discontinued at disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....