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: .....

Venetoclax

INITIATION – previously untreated chronic lymphocytic leukaemia in combination with obinutuzumab

Prerequisites (tick boxes where appropriate)

- ○ Individual is currently on treatment with venetoclax and obinutuzumab and met all of the following criteria prior to commencing treatment

or

- ○ Individual has previously untreated chronic lymphocytic leukaemia

and

- ○ Venetoclax is to be administered with obinutuzumab

and

- ○ Venetoclax is to be used to a maximum dose of 400 mg and for a total of 12 (28 day) cycles

INITIATION – previously untreated chronic lymphocytic leukaemia in combination with ibrutinib

Prerequisites (tick boxes where appropriate)

- ○ Individual is currently on treatment with venetoclax and/or ibrutinib and met all of the following criteria prior to commencing treatment

or

- ○ Individual has previously untreated chronic lymphocytic leukaemia

and

- ○ Venetoclax is to be administered in combination with ibrutinib

and

- ○ Venetoclax is to be used to a maximum dose of 400 mg and for a total of 12 (28 day) cycles

INITIATION – relapsed/refractory chronic lymphocytic leukaemia

Re-assessment required after 8 months

Prerequisites (tick boxes where appropriate)

- ○ Individual has chronic lymphocytic leukaemia requiring treatment

and

- ○ Individual has received at least one prior therapy for chronic lymphocytic leukaemia

and

- ○ The individual's disease has relapsed

and

- ○ Venetoclax to be used in combination with six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax

and

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

CONTINUATION – relapsed/refractory chronic lymphocytic leukaemia

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ Treatment remains clinically appropriate and the individual is benefitting from and tolerating treatment

and

- ○ Venetoclax is to be discontinued after a maximum of 24 months of treatment following the titration schedule unless earlier discontinuation is required due to disease progression or unacceptable toxicity

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL) and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are Unapproved indications.

I confirm that the above details are correct:

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

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: .....

Venetoclax *- continued*

INITIATION – previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Individual has previously untreated chronic lymphocytic leukaemia

and

- ○ There is documentation confirming that the individual has 17p deletion by FISH testing or TP53 mutation by sequencing

and

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

CONTINUATION – previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ No evidence of disease progression

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL)* and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are unapproved indications

INITIATION – previously untreated acute myeloid leukaemia
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ The individual is currently on treatment with venetoclax and met all remaining special authority criteria prior to commencing treatment

or

- ○ Individual has previously untreated acute myeloid leukaemia (see note a), according to World Health Organization (WHO) Classification

and

- ○ Venetoclax not to be used in combination with standard intensive remission induction chemotherapy

and

- ○ Venetoclax to be used in combination with azacitidine or low dose cytarabine

CONTINUATION – previously untreated acute myeloid leukaemia
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ No evidence of disease progression

Note:

a) 'Acute myeloid leukaemia' includes myeloid sarcoma*

b) Indications marked with * are Unapproved indications

I confirm that the above details are correct:

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