

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*

Note: *maximum number of cycles refers to 12 cycles of full dose venetoclax, in addition to the initial 5-week dose ramp-up period.

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*

Note: *maximum number of cycles refers to 12 cycles of full dose venetoclax, in addition to the initial 5-week dose ramp-up period.

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 polymorphocytic leukaemia (B-PLL)*. Indications marked with * are Unapproved indications.

I confirm that the above details are correct:

Signed: Date:

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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: