

CRITERIA FOR PRIOR AUTHORIZATION

Venclexta® (venetoclax)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Venetoclax (Venclexta®)

CRITERIA FOR INITIAL APPROVAL (must meet all of the following):

- Patient must be clinically diagnosed with Chronic lymphocytic leukemia (CLL) with 17p chromosome deletion, as detected by an FDA approved test
- Patient must have received at least one prior therapy
- The medication is prescribed by or in consultation with an oncologist or hematologist
- Patient must be 18 years of age or older
- Patient must not be on concurrent strong CYP3A4 inhibitors at initiation or ramp-up (see note below for maintenance dosing)
- Patient must not be pregnant or breastfeeding
- Dose must not exceed 400 mg per day

LENGTH OF APPROVAL: 6 months

CRITERIA FOR RENEWAL (must meet all of the following):

- Must meet initial criteria for renewal

RENEWAL LENGTH OF APPROVAL: 12 months

Notes:

- Strong CYP3A Inhibitors: For patients who have completed the ramp-up phase and are on a steady daily dose of Venclexta, reduce the Venclexta dose by at least 75% when used concomitantly with strong CYP3A4 inhibitors. Resume the Venclexta dose that was used prior to initiating the CYP3A inhibitor 2 to 3 days after discontinuation of the inhibitor. Weekly ramp up schedule is over the first 5 weeks of therapy.
- The risk of Tumor Lysis Syndrome (TLS) is based on tumor burden and comorbidities. Patients with reduced renal function (CrCl <80 mL/min) are at increased risk of Tumor Lysis Syndrome (TLS).
- Strong CYP3A4 inhibitors: Clarithromycin, telithromycin, nefazodone, itraconazole, ketoconazole, atazanavir, darunavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir.

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE

DATE

Table 2. Recommended TLS Prophylaxis Based on Tumor Burden From Clinical Trial Data (consider all patient co-morbidities before final determination of prophylaxis and monitoring schedule)

Tumor Burden		Prophylaxis		Blood Chemistry Monitoring ^{c,d}
		Hydration ^a	Anti-hyperuricemics	Setting and Frequency of Assessments
Low	All LN <5 cm AND ALC <25 x10 ⁹ /L	Oral (1.5-2 L)	Allopurinol ^b	Outpatient <ul style="list-style-type: none"> • Pre-dose, 6 to 8 hours, 24 hours at first dose of 20 mg and 50 mg • Pre-dose at subsequent ramp-up doses
Medium	Any LN 5 cm to <10 cm OR ALC ≥25 x10 ⁹ /L	Oral (1.5-2 L) and consider additional intravenous	Allopurinol	Outpatient <ul style="list-style-type: none"> • Pre-dose, 6 to 8 hours, 24 hours at first dose of 20 mg and 50 mg • Pre-dose at subsequent ramp-up doses • Consider hospitalization for patients with CrCl <80ml/min at first dose of 20 mg and 50 mg; see below for monitoring in hospital
High	Any LN ≥10 cm OR ALC ≥25 x10 ⁹ /L AND any LN ≥5 cm	Oral (1.5-2 L) and intravenous (150-200 mL/hr as tolerated)	Allopurinol; consider rasburicase if baseline uric acid is elevated	In hospital at first dose of 20 mg and 50 mg <ul style="list-style-type: none"> • Pre-dose, 4, 8, 12 and 24 hours Outpatient at subsequent ramp-up doses <ul style="list-style-type: none"> • Pre-dose, 6 to 8 hours, 24 hours

ALC = absolute lymphocyte count; LN = lymph node.
^aAdminister intravenous hydration for any patient who cannot tolerate oral hydration.
^bStart allopurinol or xanthine oxidase inhibitor 2 to 3 days prior to initiation of VENCLEXTA.
^cEvaluate blood chemistries (potassium, uric acid, phosphorus, calcium, and creatinine); review in real time.
^dFor patients at risk of TLS, monitor blood chemistries at 6 to 8 hours and at 24 hours at each subsequent ramp-up dose.