

**Venetoclax (Venclexta®)****Criteria for Use Update****April 2020**

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.**

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vaww.pbm.va.gov> for further information.

**Exclusion Criteria** *If the answer to ANY item below is met, then the patient should NOT receive venetoclax.*

- Patient is unable to comply with intense Tumor Lysis Syndrome (TLS) monitoring & hydration requirements that begin prior to first dose of venetoclax and continue during ramp-up phase
- Intolerance to BOTH xanthine oxidase inhibitors AND rasburicase
- Exhibit evidence of clinically significant conditions, including
  - Uncontrolled systemic infection
  - Active and uncontrolled autoimmune cytopenias (AIHA\*, ITP\*)
- Richter's transformation
- Severe hepatic dysfunction (Bilirubin > 3x ULN) – has not been studied
- Severe renal impairment (Clcr < 30 ml/min)

**Inclusion Criteria** *The answers to the following must be fulfilled to meet criteria under each indication*

- Venetoclax in combination with rituximab or obinutuzumab or as monotherapy for CLL/SLL:
  - Diagnosis of Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Leukemia (SLL) with/without deletion 17p
  - ANC > 1000 cells/mm<sup>3</sup> and/or platelet count > 30,000 cells/mm<sup>3</sup> unless bone marrow involvement
  - ECOG\* Performance Status 0-2
  - Must be on tumor lysis prophylaxis

**OR**

- Venetoclax in combination with either azacytidine, decitabine or low-dose cytarabine for AML:
  - Newly diagnosed Acute Myeloid Leukemia (AML)
  - And age ≥ 75 years OR are not a candidate for intensive induction chemotherapy
  - WBC < 25 x 10<sup>9</sup>/L prior to start of therapy; cytoreduction prior to therapy may be required
  - ECOG Performance Status 0-3
  - Must be on tumor lysis prophylaxis

**Additional Inclusion Criteria****AND THE FOLLOWING:**

- Care provided by a VA or VA purchased care (e.g. MISSION, Fee Basis) hematology/oncology provider.
- Goals of care and role of Palliative Care consult have been discussed and documented.
- Mandatory identification of CYP3A4 inhibitors as they are contraindicated during ramp-up phase
- Mandatory assessment of tumor burden (outpatient vs. inpatient care)

\*AIHA autoimmune hemolytic anemia; ITP idiopathic thrombocytopenic purpura; CR complete response; PR partial response; ECOG Eastern Cooperative Oncology Group