Pharmacy Policy Bulletin: J-0771 Venclexta (venetoclax) – Commercial and Healthcare Reform	
Number: J-0771	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0771-012	**Original Date:** 06/01/2016
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Venclexta (venetoclax)
FDA-Approved Indication(s):	• Treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). • In combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

Background:	• Venclexta is a selective and orally bioavailable small molecule inhibitor of B-cell lymphoma 2 (BCL-2), an anti-apoptotic protein. It helps restore apoptosis by binding directly to the BCL-2 protein, leading to displacement of pro-apoptotic proteins, trigger of mitochondrial outer membrane permeabilization and the activation of caspases.
	• The presence of the 17p deletion is the strongest adverse prognostic factor for survival.
	• Venclexta may be used in combination with Gazyva (obinutuzumab) for the treatment of CLL or SLL.
	• Prescribing Considerations
	  ○ Venclexta should be prescribed by a hematologist/oncologist.
	  ○ Concomitant use with strong CYP3A inhibitors at initiation and during ramp-up phase in patients with CLL/SLL is contraindicated.
	  ○ For AML, low-dose cytarabine refers to a 20 mg/m^2 dose once daily.

Approval Criteria

I. Initial Authorization

A. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

When a benefit, coverage of Venclexta may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member is 18 years of age or older.

2. The member has a diagnosis of one (1) of the following **(a. or b.)**:

a. CLL (ICD-10 C91.1)
b. SLL (ICD-10 C83.0)

B. Acute Myeloid Leukemia (AML)
When a benefit, coverage of Venclexta may be approved when all of the following criteria are met **(1. through 4.)**:
1. The member is 18 years of age or older.
2. The member was newly diagnosed with AML (ICD-10: C92.0)
3. The member is using Venclexta in combination with one (1) of the following **(a., b., or c.)**:
a. azacitidine
b. decitabine
c. low-dose cytarabine
4. The member has at least one (1) comorbidity that precludes use of intensive induction chemotherapy defined as one (1) of the following **(a. through e.)**:
a. Age ≥ 75 years
b. Severe cardiac or pulmonary comorbidity
c. Reduced renal function
d. Hepatic impairment
e. The prescriber attests that the member is not a candidate for intensive induction therapy.

II. Reauthorization
When a benefit, reauthorization of Venclexta may be approved when the following criterion is met **(A.)**:
A. The prescriber attests that the member is tolerating therapy and has experienced a therapeutic response defined as either one of the following **(1. or 2.)**:
1. Disease improvement
2. Delayed disease progression

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

IV. Coverage of oncology medications listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

Refer to J-479 for previous versions.

References:

1. Venclexta [package insert]. North Chicago, Illinois: AbbVie, Inc.; June 2022.
2. NCCN Guidelines. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma v.1.2025. National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed January 29, 2025.
3. NCCN Guidelines. Acute Lymphoblastic Leukemia v.3.2024. National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed January 29, 2025.
4. Gazyva [package insert]. South San Francisco, California: Genentech, Inc.; July 2022.