

Pharmacy Policy Bulletin: J-0479 Venclexta (venetoclax) – Medicare	
Number: J-0479	Category: Prior Authorization
Line(s) of Business: <input type="checkbox"/> Commercial <input type="checkbox"/> Healthcare Reform <input checked="" type="checkbox"/> Medicare	Benefit(s): Not Applicable
Region(s): <input checked="" type="checkbox"/> All <input type="checkbox"/> Delaware <input type="checkbox"/> New York <input type="checkbox"/> Pennsylvania <input type="checkbox"/> West Virginia	Additional Restriction(s): Applies to new starts only for protected indications
Version: J-0479-013	Original Date: 06/01/2016
Effective Date: 04/22/2024	Review Date: 04/03/2024

Drugs Product(s):	<ul style="list-style-type: none"> Venclexta (venetoclax)
FDA-Approved Indication(s):	<ul style="list-style-type: none"> Treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Treatment of newly diagnosed acute myeloid leukemia (AML), in combination with azacitidine or decitabine or low dose cytarabine in adult patients who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.

Background:	<ul style="list-style-type: none"> 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 (process in which cancer cells self-destruct) 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. There are limited antineoplastic medications specific to CLL with 17p deletion. Venclexta may be used in combination with Gazyva (obinutuzumab) for the treatment of CLL or SLL. Prescribing Considerations <ul style="list-style-type: none"> 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/m² dose once daily.
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Approval Criteria

I. Approval Criteria

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
- b. SLL

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 is newly diagnosed with AML.
- 3. The member is using Venclexta in combination with one 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 preclude use of intensive induction chemotherapy defined as one (1) of the following **(a. through e.)**:
 - a. Age \geq 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. For Medicare Part D beneficiaries, drug(s) addressed in this policy may be approved when used for a medically accepted indication as defined by the Centers for Medicare & Medicaid Services (CMS).

Limitations of Coverage

None

Authorization Duration

- Medicare Part D Plans: If approved, a 12 month authorization will be granted.

Automatic Approval Criteria

None

References:

- 1. Venclexta [package insert]. North Chicago, Illinois: AbbVie, Inc.; June 2022.
- 2. NCCN Guidelines. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma v.1.2024. National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed February 20, 2024.
- 3. NCCN Guidelines. Acute Lymphoblastic Leukemia v.6.2023. National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed February 20, 2024.
- 4. Gazyva [package insert]. South San Francisco, California: Genentech, Inc.; July 2022.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.