

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Venclexta (venetoclax)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Venclexta (venetoclax)	May be subject to quantity limit

### APPROVAL CRITERIA

Requests for Venclexta (venetoclax) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL); **AND**
- II. Individual is using in combination with obinutuzumab for first-line treatment in individuals with or without del(17p)/TP53 mutation (NCCN 2A);

**OR**

- III. Individual has a diagnosis of relapsed/refractory Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) with or without del(17p)/TP53 mutation; **AND**
- IV. Individual is using in combination with rituximab (or rituximab biosimilar);

**OR**

- V. Individual is using as monotherapy;

**OR**

- VI. Individual has a diagnosis of newly-diagnosed Acute Myeloid Leukemia (AML); **AND**
- VII. Individual is 75 years of age or older or individual has comorbidities that preclude the use of intensive induction chemotherapy; **AND**
- VIII. Individual is using in combination with azacitidine, or decitabine, or low-dose cytarabine;

**OR**

- IX. Individual has a diagnosis of Mantle Cell Lymphoma (NCCN 2A); **AND**
- X. Individual is using as monotherapy.

**Note:** Concomitant use of Venclexta (venetoclax) with strong inhibitors of CYP3A at initiation and during ramp-up phase in those with CLL/SLL is contraindicated.

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**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 22, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 12, 2019.
  - a. B-Cell Lymphomas. V7.2019. Revised December 18, 2019.
  - b. Chronic Lymphocytic Leukemia/small lymphocytic lymphoma. V4.2020. Revised December 20, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.