

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 for the following:
 - A. Individuals with del (17p) mutation (NCCN 2A); **OR**
 - B. Individuals without del (17p) mutation who are frail, age ≥ 65 years, or with significant comorbidities (NCCN 2A);
- OR**
- III. Individual has a diagnosis of relapsed/refractory Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) with or without 17p deletion; **AND**
 - IV. Individual is using in combination with rituximab; **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.

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.

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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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	NA	NA

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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: May 31, 2019.
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 May 31, 2019.
 - a. Chronic Lymphocytic Leukemia/small lymphocytic lymphoma. V5.2019. Revised May 23, 2019.

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