

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 or retreatment 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 60 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 acute myeloid leukemia (AML) (NCCN 2A); **AND**
- X. Individual is using in combination with azacitidine or decitabine or low-dose cytarabine;

OR

- XI. Individual has a diagnosis of Waldenstrom Macroglobulinemia/ Lymphoplasmacytic lymphoma; **AND**
- XII. Individual has progressive or relapsed disease or has not responded to primary therapy; **AND**
- XIII. Individual is using as monotherapy;

OR

- XIV. Individual has a diagnosis of previously treated Mantle Cell Lymphoma (NCCN 2A); **AND**

XV. Individual is using as monotherapy or in combination with ibrutinib or in combination with rituximab;

OR

XVI. Individual has a diagnosis of relapsed or refractory t(11;14) systemic light chain amyloidosis (NCCN 2A); **AND**

XVII. Individual had disease progression on at least one prior line of therapy (Premkumar 2021); **AND**

XVIII. Individual is using as a single agent or in combination with dexamethasone;

OR

XIX. Individual has a diagnosis of relapse or progressive t(11;14) multiple myeloma (NCCN 2A); **AND**

XX. Individual has received at least one prior line of therapy; **AND**

XXI. Individual is using Venclexta in combination with dexamethasone.

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.

Key References:

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
3. DiNardo CD, Rausch CR, Benton C, et al. Clinical experience with the BCL2-inhibitor venetoclax in combination therapy for relapsed and refractory acute myeloid leukemia and related myeloid malignancies. *Am J Hematol*. 2018;93(3):401-407.
4. DiNardo CD, Jonas BA, Pullarkat V, et al. Azacitidine and venetoclax in previously untreated acute myeloid leukemia. *N Engl J Med* 2020; 383:617-629.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
7. Premkumar VJ, Lentzsch S, Pan S, et al. Venetoclax induces deep hematologic remissions in t(11;14) relapsed/refractory AL amyloidosis. *Blood Cancer J*. 2021;11(1):10.
8. Basali D, Chakraborty R, Rybicki L, et al. Real-world data on safety and efficacy of venetoclax-based regimens in relapsed/refractory t(11;14) multiple myeloma. *Br J Haematol*. 2020;189(6):1136-1140.
9. Kaufman JL, Gasparetto C, Schjesvold FH, et al. Targeting BCL-2 with venetoclax and dexamethasone in patients with relapsed/refractory t(11;14) multiple myeloma. *Am J Hematol*. 2021;96(4):418-427. doi:10.1002/ajh.26083 Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7986778/>. Accessed July 11, 2023.
10. Kumar S, Kaufman JL, Gasparetto C, et al. Efficacy of venetoclax as targeted therapy for relapsed/refractory t(11;14) multiple myeloma. *Blood*. 2017;130(22):2401-2409.
11. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 21, 2023.
 - a. Chronic Lymphocytic Leukemia/small lymphocytic lymphoma. V3.2022. Revised June 3, 2022.
 - b. Acute Myeloid Leukemia. V2.2022. Revised June 14, 2022.
 - c. B-Cell Lymphomas. V4.2022. Revised June 9, 2022.
 - d. Multiple Myeloma. V5.2022. Revised March 9, 2022.
 - e. Systemic Light Chain Amyloidosis. V1.2022. Revised June 29, 2021.
 - f. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma. V3.2022. Revised May 2, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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