

<b>Clinical Policy Title:</b>	venetoclax
<b>Policy Number:</b>	RxA.617
<b>Drug(s) Applied:</b>	Venclexta®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) (must meet all):

1. Diagnosis of chronic lymphocytic leukemia or small lymphocytic leukemia.

##### Approval Duration

**All lines of business (except Medicare): 12 months**

#### B. Acute Myeloid Leukemia (must meet all):

1. Diagnosis of acute myeloid leukemia;
2. Disease is newly diagnosed;
3. Member meets one of the following (a or b):
  - a. Age  $\geq$  75 years;
  - b. Comorbidities that prevent use of intensive induction chemotherapy
4. Prescribed in combination with azacitidine, decitabine, or low-dose cytarabine.

##### Approval Duration

**All lines of business (except Medicare): 12 months**

### II. Continued Therapy Approval

#### A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

##### Approval Duration

**All lines of business (except Medicare): 12 months**

## References

1. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 2.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/cll.pdf](https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf). Accessed March 25, 2025.
2. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 2.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/aml.pdf](https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf). Accessed March 25, 2025.
3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 2.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/b-cell.pdf](https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf). Accessed March 25, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
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This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Policy established.	03/2020	03/06/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Clinical policy title table was updated.</li> <li>2. Commercial approval duration was updated for initial approval criteria from “length of benefit” to “6 months”.</li> <li>3. Commercial approval duration was updated for continued approval criteria from “length of benefit” to “12 months”.</li> <li>4. Initial Approval criteria I.A.2 added.</li> <li>5. Off label indication Added: Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) AML</li> <li>6. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by Rxadvance...”.</li> <li>7. References were reviewed and updated.</li> </ol>	12/03/2020	12/07/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.C.4 was updated to include “Must be prescribed as (a or b): as a single agent or; in combination with rituximab”.</li> <li>2. Initial Approval Criteria I.D.4 was clarified to “Must be prescribed in combination with azacitidine, decitabine, or low-dose cytarabine for patients with (a or b):”</li> <li>3. Initial Approval Criteria I.A.2 was updated to remove “Request is for one of the following (a or b); Without del(17p)/TP53 mutation in frail patients with significant comorbidity (not able to tolerate purine analogs) or age ≥ 65 years and younger patients with or without significant comorbidities; With del(17p)/TP53 mutation;”</li> <li>4. Initial Approval criteria I.E was updated to include off label indication “Multiple Myeloma”.</li> <li>5. Initial Approval criteria I.F was updated to include off label indication “Systemic Light Chain Amyloidosis”.</li> <li>6. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently</li> </ol>	10/19/2021	12/07/2021

<p>receiving medication that has been authorized by RxAdvance...".</p> <p>7. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <p>1. References were reviewed and updated.</p>	09/06/2022	10/19/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>Updated disease diagnosis age criteria from Age ≥ 60 years to ≥ 75 years for Acute Myeloid Leukemia.</li> <li>Updated to remove relapsed and remission criteria to Venclexeta and indication therapy for Acute Myeloid Leukemia.</li> <li>Updated to add new combination criteria in combination with azacitidine, decitabine, or low-dose cytarabine for Acute Myeloid Leukemia.</li> <li>Updated to remove lab and disease status criteria for Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) AML.</li> <li>Updated to remove requesting criteria for previously treated multiple myeloma for relapse or progressive disease.</li> <li>Updated to add new prescribing criteria in combination with dexamethasone with or without daratumumab, bortezomib, carfilzomib, or ixazomib for multiple myeloma.</li> <li>Updated to add new criteria prescribed as single agent for Systemic Light Chain Amyloidosis (off-label) indication.</li> <li>References were reviewed and updated.</li> </ol>	12/18/2023	01/01/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>Removed prescriber criteria.</li> <li>Updated continuation of therapy language.</li> <li>References were reviewed and updated.</li> </ol>	03/25/2025	04/10/2025
<p>Policy reviewed.</p>	12/11/2025	12/11/2025