Clinical Policy Title:	venetoclax
Policy Number:	RxA.617
Drug(s) Applied:	Venclexta®
Original Policy Date:	03/06/2020
Last Review Date:	01/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (must meet all)**:**

1. Diagnosis of CLL or SLL;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Request meets one of the following (a or b):
   a. Prescribed in combination with Gazyva® as first-line therapy;
   b. Member meets (i and ii):
      i. Prescribed as monotherapy or in combination with rituximab;
      ii. Disease is relapsed or refractory after at least one prior therapy.

Approval Duration
All lines of business (except Medicare): 12 months

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

1. Diagnosis of AML;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Member meets one of the following (a, b, or c):
   a. Disease is newly diagnosed and (i or ii):
      i. Age ≥ 75 years;
      ii. 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

C. Mantle Cell Lymphoma (off-label) (must meet all)**:**

1. Diagnosis of mantle cell lymphoma;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Must be prescribed as (a or b):
   a. As a single agent or;
   b. In combination with rituximab or ibrutinib;
4. Member has received ≥ 1 prior therapy.

Approval Duration
All lines of business (except Medicare): 12 months

D. Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) AML (off-label) (must meet all)**:**
1. Diagnosis of Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) AML;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Must be prescribed in combination with azacitidine, decitabine, or low-dose cytarabine.

Approval Duration
All lines of business (except Medicare): 12 months

E. Multiple Myeloma (off-label) (must meet all)**:**
1. Diagnosis of Multiple Myeloma;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Prescribed in combination with dexamethasone with or without daratumumab, bortezomib, carfilzomib, or ixazomib.

Approval Duration
All lines of business (except Medicare): 12 months

F. Systemic Light Chain Amyloidosis (off-label) (must meet all)**:**
1. Diagnosis of Systemic Light Chain Amyloidosis;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Prescribed as single agent or in combination with dexamethasone.

Approval Duration
All lines of business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**
Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration
All lines of business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymophoma Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed December 18, 2023.
2. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf Accessed December 18, 2023.
3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 5.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed December 18, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title table was updated. 2. Commercial approval duration was updated for initial approval criteria from “length of benefit” to “6 months”. 3. Commercial approval duration was updated for continued approval criteria from “length of benefit” to “12	12/03/2020	12/07/2020

months". 4. Initial Approval criteria I.A.2 added. 5. Off label indication Added: Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) AML 6. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by Rxadvance…". 7. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Critiera I.C.4 was updated to include "Must be prescribed as (a or b): as a single agent or; in combination with rituximab". 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):" 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(17)p/TP53 mutation;" 4. Initial Approval criteria I.E was updated to include off label indication "Multiple Myeloma". 5. Initial Approval criteria I.F was updated to include off label indication "Systemic Light Chain Amyloidosis". 6. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 7. References were reviewed and updated.	10/19/2021	12/07/2021
Policy was reviewed: 1. References were reviewed and updated.	09/06/2022	10/19/2022
Policy was reviewed: 1. Updated disease diagnosis age criteria from Age ≥ 60 years to ≥ 75 years for Acute Myeloid Leukemia.	12/18/2023	01/01/2024

2. Updated to remove relapsed and remission criteria to Venclexeta and indication therapy for Acute Myeloid Leukemia. 3. Updated to add new combination criteria in combination with azacitidine, decitabine, or low-dose cytarabine for Acute Myeloid Leukemia. 4. Updated to remove lab and disease status criteria for Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) AML. 5. Updated to remove requesting criteria for previously treated multiple myeloma for relapse or progressive disease. 6. Updated to add new prescribing criteria in combination with dexamethasone with or without daratumumab, bortezomib, carfilzomib, or ixazomib for multiple myeloma. 7. Updated to add new criteria prescribed as single agent for Systemic Light Chain Amyloidosis (off-label) indication. 8. References were reviewed and updated.		