PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Venclexta Prior Authorization Policy
- Venclexta® (venetoclax tablets – AbbVie and Genentech)

REVIEW DATE: 07/19/2023

OVERVIEW

Venclexta, a B-cell lymphoma-2 inhibitor, is indicated in adults for the following uses:[1]

- **Acute myeloid leukemia (AML)**, in combination with azacitidine or decitabine or low-dose cytarabine for newly diagnosed AML in patients ≥ 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy.
- **Chronic lymphocytic leukemia (CLL)**.
- **Small lymphocytic lymphoma (SLL)**.

Guidelines

Venclexta is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **AML**: NCCN guidelines (version 4.2023 – July 11, 2023) recommend Venclexta (in combination with decitabine, azacitidine or low-dose cytarabine) in a variety of clinical scenarios, such as induction therapy, post induction therapy, and relapsed or refractory disease. The guidelines recommend Venclexta (in combination with decitabine, azacitidine, or low-dose cytarabine) (category 2A) for Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) for systemic disease treated with palliative intent (patients with low performance and/or nutritional status) or relapsed/refractory disease.
- **B-Cell Lymphomas**: NCCN guidelines (version 5.2023 – July 7, 2023) address mantle cell lymphoma.[3] The guidelines cite Venclexta (continuous) ± rituximab (category 2A), Venclexta + Imbruvica® (ibrutinib tablets, capsules, and oral solution) [category 2A] as second-line therapy regimens as "useful in certain circumstances".
- **CLL/SLL**: NCCN guidelines (version 3.2023 – June 12, 2023) cite Venclexta in several scenarios.[4] For patients without 17p deletion/TP53 mutation, Venclexta + Gazyva® (obinutuzumab intravenous infusion) is listed as a "preferred" first-line therapy (category 1); Venclexta + rituximab is listed as a "preferred regimen" (category 1) and single-agent Venclexta is listed as "other recommended regimen" (category 2A) for second-line or third-line therapy.[3] For patients with 17p deletion/TP53 mutation, Venclexta + Gazyva is recommended as a "preferred regimen" first-line (category 2A); Venclexta + rituximab (category 1) and single-agent Venclexta (category 2A) are preferred second-line and subsequent therapy in this population. Many other first-line options are recommended. CLL and SLL are different manifestations of the same disease which are managed similarly.
- **Multiple Myeloma:** NCCN guidelines (version 3.2023 – December 8, 2022) recommend Venclexta + dexamethasone for previously treated multiple myeloma for relapse or progressive disease for patients with t (11;14) translocation as "useful in certain circumstances for early relapses (1-3 prior therapies) [category 2A].[5]
- **Systemic Light Chain Amyloidosis:** NCCN guidelines (version 2.2023 – November 28, 2022) list Venclexta ± dexamethasone as a therapy for previously treated disease for patients with t (11;14) translocation as "useful in certain circumstances" (category 2A).[6]
- **Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma:** NCCN guidelines (version 1.2023 – July 6, 2022) recommend single-agent Venclexta as "other recommended regimen" for previously treated disease (category 2A).[4-5]

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POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Venclexta. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Venclexta is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets the following (A and B):
   Note: Acute Myeloid Leukemia includes Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN).
   A) Patient is ≥ 18 years of age; AND
   B) Venclexta is used in combination with either azacitidine, decitabine, or cytarabine.

2. **Chronic Lymphocytic Leukemia.** Approve for 1 year if the patient is ≥ 18 years of age.

3. **Small Lymphocytic Lymphoma.** Approve for 1 year if the patient is ≥ 18 years of age.

Other Uses with Supportive Evidence

4. **Mantle Cell Lymphoma.** Approve for 1 year if the patient meets the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least one systemic regimen.
   Note: Examples of systemic regimens include those containing one or more of the following products: Imbruvica (ibrutinib tablets, capsules, and oral solution), rituximab, Calquence (acalabrutinib tablets), lenalidomide, dexamethasone, cytarabine, cisplatin, cyclophosphamide, doxorubicin, vincristine, high-dose methotrexate, cytarabine, or Treanda (bendamustine intravenous infusion).

5. **Multiple Myeloma**. Approve for 1 year if the patient meets the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has t (11;14) translocation; AND
   C) Patient has tried at least one systemic regimen for multiple myeloma; AND
   Note: Examples of systemic regimens include those containing one or more of the following products: bortezomib, Kyprolis (carfilzomib intravenous injection), lenalidomide, cyclophosphamide, or Ninlaro (ixazomib capsules).
   D) Venclexta is used in combination with dexamethasone.

6. **Systemic Light Chain Amyloidosis.** Approve for 1 year if the patient meets the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has t (11;14) translocation; AND
   C) Patient has tried at least one systemic regimen.
   Note: Examples of systemic regimens include those containing one or more of the following products: bortezomib, lenalidomide, cyclophosphamide, and melphalan.

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7. **Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma.** Approve for 1 year if the patient meets the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least one systemic regimen.
   Note: Examples of a systemic regimen contain one or more of the following products: Brukinsa (zanubrutinib capsules), Imbruvica (ibrutinib tablets, capsules, and oral solution), rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, fludarabine, or cladribine.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Venclexta is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Venclexta® tablets [prescribing information]. North Chicago, IL and South San Francisco, CA: AbbVie and Genentech; June 2022.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 4.2023 – July 11, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 14, 2023.
3. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 5.2023 – July 7, 2023). © 2023 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on July 14, 2023.
4. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 3.2023 – June 12, 2023). © 2023 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on July 14, 2023.
5. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2023 – December 8, 2022). © 2022 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on July 14, 2023.
6. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (version 2.2023 – November 28, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 14, 2023.
7. The NCCN Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2023 – July 6, 2022). © 2022 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on July 14, 2023.

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