PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/13/2022

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 2.2022 – June 14, 2022) recommend Venclexta (in combination with decitabine, azacitidine or low-dose cytarabine) for treatment induction in patients ≥ 60 years of age who are candidates for intensive remission induction therapy with unfavorable-risk cytogenetics (category 2A).[2] The guidelines cite Venclexta in other induction therapy clinical scenarios in patients who are not candidates for intensive remission. The guidelines recommend Venclexta (in combination with decitabine, azacitidine, or low-dose cytarabine) for post-induction therapy for patients who are ≥ 60 years of age. NCCN guidelines recommend Venclexta (in combination with decitabine, azacitidine, or low-dose cytarabine) for relapsed and refractory disease for patients who are ≥ 18 years of age. 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 4.2022 – June 9, 2022) address mantle cell lymphoma.[3] The guidelines cite Venclexta ± rituximab (category 2A), Venclexta + Imbruvica® (ibrutinib tablets and capsules) [category 2A], and Venclexta + lenalidomide +rituximab (category 2B) as second-line therapy regimens, useful in certain circumstances.
- **CLL/SLL**: NCCN guidelines (version 3.2022 – June 3, 2022) 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 for patients ≥ 65 years of age (category 1) and for patients < 65 years of age with significant comorbidities (category 1) or without significant comorbidities (category 2A); Venclexta + rituximab is listed as a preferred regimen (category 1) and single-agent Venclexta is listed as other recommended regimen (category 2A) for patients with relapsed/refractory disease.[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 5.2022 – March 9, 2022) cite Venclexta + dexamethasone for previously treated multiple myeloma for relapse or progressive disease for patients with t (11;14) translocation (category 2A).[5]

- **Systemic Light Chain Amyloidosis:** NCCN guidelines (version 1.2022 – June 29, 2021) list Venclexta ± dexamethasone as a therapy for previously treated disease, for patients with t (11;14) translocation (category 2A).[6]
- **Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma:** NCCN guidelines (version 1.2023 – July 6, 2022) recommend single-agent Venclexta as an Other Recommended Regimen for previously treated disease (category 2A).[4-5]

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 criteria (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 criteria (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 capsules and tablets), rituximab, Calquence (acalabrutinib capsules), 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 criteria (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 criteria (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.

7. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma. Approve for 1 year if the patient meets the following criteria (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 and capsules), 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 2.2022 – June 14, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 8, 2022.
3. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2022 – June 9, 2022). © 2022 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on July 8, 2022.
4. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 3.2022 – June 3, 2022). © 2022 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on July 8, 2022.
5. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 5.2022 – March 9, 2022). © 2022 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on July 8, 2022.
6. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (version 1.2022 – June 29, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 8, 2022.
7. The NCCN Waldenstrom 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 8, 2022.