

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Venclexta Prior Authorization Policy

- Venclexta® (venetoclax tablets – AbbVie and Genentech)

REVIEW DATE: 06/23/2021

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 3.2021 – March 2, 2021) 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.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. 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 4.2021 – May 5, 2021) address mantle cell lymphoma.³ The guidelines cite single agent Venclexta (category 2A), Venclexta in combination with rituximab (category 2A), and Venclexta with Imbruvica (ibrutinib tablets and capsules) (category 2B). as a second-line therapy regimen, useful in certain circumstances (category 2A).
 - **CLL/SLL:** NCCN guidelines (version 4.2021 – April 29, 2021) cite Venclexta in several scenarios.⁴ Venclexta plus Gazyva® (obinutuzumab injection for intravenous use) is listed as a first-line therapy (preferred regimen) in frail patients with significant comorbidities, patients ≥ 65 years, and in younger patients with significant comorbidities without 17p deletion/TP53 mutation (category 1). This regimen is also cited as another recommended regimen (category 2A) in patients < 65 years of age without significant comorbidity. Venclexta plus rituximab is listed as preferred regimen option for patients with relapsed/refractory therapy without 17p deletion/TP53 mutation (category 1). NCCN also cite Venclexta as an option for relapsed/refractory therapy among patients with CLL without 17p deletion/TP53 mutation (category 2A).³ For patients with 17p deletion/TP53 mutation, Venclexta plus Gazyva is recommended as a preferred regimen first-line (category 2A). Also, among this population, NCCN recommends Venclexta with rituximab (category 1) and Venclexta single-agent (category 2A) as preferred second-line and subsequent therapy. Many other first-line options
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are recommended. CLL and SLL are different manifestations of the same diseases which are managed similarly.

- **Multiple Myeloma:** NCCN guidelines (version 7.2021 – April 26, 2021) cite Venclexta in combination with dexamethasone (category 2A) for previously treated multiple myeloma for relapse or progressive disease for patients with t(11;14) translocation.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 the following criteria:

FDA-Approved Indications

1. **Acute Myeloid Leukemia (AML).** Approve for 3 years 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 (CLL).** Approve for 3 years if the patient is ≥ 18 years of age.
3. **Small Lymphocytic Lymphoma (SLL).** Approve for 3 years if the patient is ≥ 18 years of age.

Other Uses with Supportive Evidence

4. **Mantle Cell Lymphoma.** Approve for 3 years 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), Revlimid (lenalidomide capsules), dexamethasone, cytarabine, cisplatin, cyclophosphamide, doxorubicin, vincristine, high-dose methotrexate, cytarabine, or Treanda (bendamustine injection for intravenous use).
 5. **Multiple Myeloma.** Approve for 3 years 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 injection), Revlimid (lenalidomide capsules), cyclophosphamide, or Ninlaro (ixazomib capsules).
D) Venclexta is used in combination with dexamethasone.
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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 (a member of the Roche Group); November 2020.
 2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2021– March 2, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on June 9, 2021.
 3. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2021 – May 5, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at <http://www.nccn.org>. Accessed on June 9, 2021.
 4. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 4.2021 – April 29, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at <http://www.nccn.org>. Accessed on June 9, 2021.
 5. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 7.2021 – April 26, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at <http://www.nccn.org>. Accessed on June 9, 2021.
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