VENTURA COUNTY
HEALTH CARE PLAN

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

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.

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.