UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Venclexta

Program	Prior Authorization
Medication	Venclexta (venetoclax)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania –CHIP, Rhode Island, South Carolina
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Venclexta (venetoclax) is a BCL-2 inhibitor indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Venclexta is also indicated in combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy.

In addition, the National Cancer Comprehensive Network (NCCN) also recommends the use of Venclexta in CLL/SLL with or without 17p deletion or TP53 mutation as second line therapy for mantle cell lymphoma. NCCN also recommends Venclexta in patients at least 60 years of age with newly diagnosed AML or relapsed/refractory disease.

2. Coverage Criteria:

A. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)

1. Initial Authorization

a. Venclexta will be approved based on the following criteria:

(1) Diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

Authorization will be issued for 12 months.

2. Reauthorization

a. Venclexta will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Venclexta therapy

Authorization will be issued for 12 months.

B. Mantle Cell Lymphoma

1. Initial Authorization

a. Venclexta will be approved based on **both** of the following criteria:

(1) Diagnosis of mantle cell lymphoma (MCL)

-AND-

(2) **Not** used as first line therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. Venclexta will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Venclexta therapy

Authorization will be issued for 12 months.

C. Acute Myeloid Leukemia (AML)

1. Initial Authorization

a. Venclexta will be approved based on **all** of the following criteria:

(1) **One** of the following:

(a) **All** of the following:

i. Diagnosis of newly-diagnosed acute myeloid leukemia (AML)

-AND-

ii. Venclexta therapy to be given in combination **one** of the following:

- Azacitidine
- Decitabine
- Low-dose cytarabine

-AND-

iii. **One** of the following:

- Patient is ≥ 60 years old
- Patient has significant comorbidities that preclude the use of intensive induction chemotherapy.

-OR-

(b) **All** of the following:

i. Diagnosis of relapsed/refractory acute myeloid leukemia (AML)

-AND-

ii. Relapse is ≥ 12 months from most recent disease remission

-AND-

iii. Venclexta therapy to be given in combination with the patient's previous initial successful induction regimen (e.g., azacitidine, decitabine, low-dose cytarabine, etc.)

Authorization will be issued for 12 months.

2. Reauthorization

a. Venclexta will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Venclexta therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

1. Initial Authorization

a. **Venclexta** will be approved for uses not outlined above if supported by The

National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. <u>Reauthorization</u>

a. **Venclexta** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Venclexta therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Venclexta [package insert]. North Chicago, IL: AbbVie Inc. July 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 24, 2020.

Program	Prior Authorization –Venclexta (venetoclax)
Change Control	
Date	Change
5/2016	New program approved by FDA on 4/11/2016.
6/2016	Added SLL to criteria per NCCN. Updated background and references.
5/2017	Removed requirement for 17p deletion or TP53 mutation for CLL/SLL and added criteria for MCL per NCCN guidelines. Updated background and references.
5/2018	Added NCCN recommended regimen criteria. Updated references.
4/2019	Added coverage for AML. Updated background and references.
4/2020	Updated background and criteria to align with updated labeled indication for first line use in CLL/SLL. Updated references.