UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1186-6
Program	Prior Authorization/Notification
Medication	Venclexta® (venetoclax)
P&T Approval Date	5/2016, 5/2017, 5/2018, 4/2019, 4/2020, 4/2021
Effective Date	7/1/2021; Oxford only: 7/1/2021

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, in patients at least 60 years of age with newly diagnosed AML or relapsed/refractory disease, and in previously treated multiple myeloma for relapse or progressive disease in combination with dexamethasone for patients with t(11;14) translocation.[2]

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. <u>Patients less than 19 years of age</u>

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

a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. <u>Acute Myeloid Leukemia (AML)</u>

1. <u>Initial Authorization</u>

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.

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

1. Initial Authorization

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

(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.

C. 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.

D. Multiple Myeloma

1. Initial Authorization

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

(1) Diagnosis of relapsed or progressive multiple myeloma which has been previously treated

-AND-

(2) Used in combination with dexamethasone

-AND-

(3) Patient has t(11;14) translocation

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.

E. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

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. November 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 18, 2021.

Program	Prior Authorization/Notification - Venclexta (venetoclax)
Change Control	
5/2016	New program approved by FDA on 4/11/2016. Added SLL to criteria per NCCN. Updated background and references.
5/2017	Annual review. Removed requirement for 17p deletion or TP53 mutation for CLL/SLL and added criteria for MCL per NCCN guidelines. Updated references.
5/2018	Annual review. No changes to criteria. Updated references.
4/2019	Annual review. Added coverage for AML based on prescribing information and NCCN guidelines. Updated references.
4/2020	Annual review. Updated background and criteria to align with updated labeled indication for first line use in CLL/SLL. Added general NCCN recommendations for use criteria. Updated references.
4/2021	Annual review. Updated background and criteria for multiple myeloma based on NCCN recommendations. Updated references.