UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1186-8
Program	Prior Authorization/Notification
Medication	Venclexta® (venetoclax)
P&T Approval Date	5/2016, 5/2017, 5/2018, 4/2019, 4/2020, 4/2021, 4/2022, 4/2023
Effective Date	7/1/2023; Oxford only: 7/1/2023

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) recommends the use of Venclexta in relapsed/refractory Philadelphia-chromosome negative acute lymphoblastic leukemia (ALL) in combination with decitabine, hyperCVAD (hyper-fractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone, alternating with high-dose methotrexate and cytarabine), nelarabine, or mini-hyperCVD (mini-hyper-fractionated cyclophosphamide, vincristine, and dexamethasone, alternating with high-dose methotrexate and cytarabine); in AML for patients less than 60 years old as alternative induction treatment with unfavorable risk genetics and TP53-mutation in combination with azacitidine, or at least 60 years of age with newly diagnosed or relapsed/refractory disease; in CLL/SLL with or without del(17p)/TP53 mutation; in multiple myeloma for relapse or progressive disease with t(11;14) translocation in combination with dexamethasone; in relapsed/refractory systemic light chain amyloidosis with t(11;14) translocation; and in previously treated Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma.

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,b]:

A. Patients less than 19 years of age

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. Acute Lymphoblastic Leukemia (ALL)

1. **Initial Authorization**

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

(1) Diagnosis of relapsed/refractory acute lymphoblastic leukemia (ALL)

-AND-

(2) ALL is Philadelphia-chromosome negative (Ph-negative)

-AND-

(3) Venclexta therapy to be given in combination with **one** of the following:

(a) Decitabine
(b) HyperCVAD
(c) Nelarabine
(d) Mini-hyperCVD

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 newly diagnosed acute myeloid leukemia (AML)

-AND-

ii. Patient is < 60 years old with unfavorable risk genetics and TP53-mutation

-AND-

iii. Venclexta therapy to be given in combination with azacitidine.

-OR-

(c) **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. 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.

E. 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.

F. 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.

G. Systemic Light Chain Amyloidosis

1. **Initial Authorization**

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

(1) Diagnosis of relapsed/refractory systemic light chain amyloidosis

-AND-

(2) 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.

H. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma

1. **Initial Authorization**

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

(1) Diagnosis of Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma which has been previously treated

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.

I. 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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

[b] Coverage of oncology medications may be approved based on state mandates.

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. June, 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 28, 2023.

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.
4/2022	Annual review. Updated background and criteria to include acute lymphoblastic leukemia, systemic light chain amyloidosis, and Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma based on NCCN recommendations. Updated references.
4/2023	Annual review. Updated background. Specified Ph-neg disease in ALL. Added additional AML recommendations. Added state mandate and oncology medications footnote. Updated references.