UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Venclexta

Program	Prior Authorization
Medication	Venclexta (venetoclax)
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	5/2017
Effective Date	7/2017

1. Background:

Venclexta (venetoclax) is a BCL-2 inhibitor indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA approved test, who have received at least one prior therapy. [1]

In addition, the National Cancer Comprehensive Network (NCCN) also recommends the use of Venclexta in small lymphocytic lymphoma (SLL) with or without 17p deletion or TP53 mutation as well as second line therapy for mantle cell lymphoma.[2]

2. Coverage Criteria:

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

1. <u>Initial Authorization</u>

a. Venclexta will be approved based on **<u>both</u>** of the following criteria:

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

-AND-

(2) Patient has received at least one prior therapy for CLL/SLL [e.g., Cytoxan (cyclophosphamide), Fludara (fludarabine), Rituxan (rituximab)]

Authorization will be issued for 12 months.

2. <u>Reauthorization</u>

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 [off label]

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.

3. References:

1. Venclexta [package insert]. North Chicago, IL: AbbVie Inc. April 2016.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 21, 2017.

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.