UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Imbruvica

Program	Prior Authorization
Medication	Imbruvica™ (ibrutinib)
Issue Date	3/2014
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

1. Background:

Imbruvica® (ibrutinib) is a kinase inhibitor indicated for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. Additionally, Imbruvica is labeled in treatment of the following: chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL); CLL/SLL with 17p deletion; Waldenström's macroglobulinemia (WM); marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy; and chronic graft versus host disease after failure of one or more lines of systemic therapy.[1]

2. Coverage Criteria:

A. Non-Hodgkin's Lymphoma (NHL)

1. Initial Authorization

a. Imbruvica will be approved based on **one** of the following criteria:

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

(a) Diagnosis of mantle cell lymphoma (MCL)

-AND-

(b) Patient has received at least one prior therapy for MCL [e.g., Rituxan (rituximab)]

-OR-

(2) Diagnosis of **one** of the following:

(a) Chronic Lymphocytic Leukemia (CLL)

-OR-

(b) Small Lymphocytic Lymphoma (SLL)

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

Authorization will be issued for 12 months.

B. Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma

1. **Initial Authorization**

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

(1) Diagnosis of Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

Authorization will be issued for 12 months.

C. Marginal Zone Lymphoma (MZL)

1. **Initial Authorization**

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

(1) Diagnosis of marginal zone lymphoma (MZL)

-AND-

(2) Patient has received at least one prior anti-CD20-based therapy for MZL [e.g., Rituxan (rituximab), Zevalin (ibritumomab), Gazyva (obinutuzumab), etc.]

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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

Authorization will be issued for 12 months.

D. Chronic Graft Versus Host Disease

1. Initial Authorization

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

(1) Diagnosis of chronic graft versus host disease

-AND-

(2) History of failure of at least one other systemic therapy [e.g. corticosteroids, mycophenolate, etc.]

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Patient shows evidence of positive clinical response while on Imbruvica therapy

Authorization will be issued for 12 months.

3. References:

1. Imbruvica [package insert]. Sunnyvale, CA: Pharmacyclics, LLC. August 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed January 30, 2017.

Change Control	
March 2014	New Criteria
December 2014	Guideline updated with new indication Chronic Lymphocytic Leukemia with 17p deletion.
June 2015	• Clarified Small Lymphocytic Leukemia (SLL) criteria to allow Imbruvica as first line use for SLL with 17p deletion. • Guideline updated with new indication for Waldenström's Macroglobulinemia (WM). • Previous off-label citeria for WM/Lymphoplasmacytic Lymphoma (LL) has been updated to allow for first-line therapy with Imbruvica based on NCCN guidelines and FDA labeling.
April 2016	• Moved MCL, CLL and SLL criteria under the general diagnosis of NHL section • Updated policy template
March 2017	• Updated policy template. • Added coverage for MZL. • Updated background and references.
September 2017	• Added new indication of chronic graft versus host disease. Updated background and references.