

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.

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Change Control	
March 2014	New Criteria
December 2014	Guideline updated with new indication Chronic Lymphocytic Leukemia with 17p deletion.
June 2015	<ul style="list-style-type: none"> • 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 criteria 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	<ul style="list-style-type: none"> • Moved MCL, CLL and SLL criteria under the general diagnosis of NHL section • Updated policy template
March 2017	<ul style="list-style-type: none"> • Updated policy template. • Added coverage for MZL. • Updated background and references.
September 2017	<ul style="list-style-type: none"> • Added new indication of chronic graft versus host disease. Updated background and references.