UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Imbruvica

Program	Prior Authorization
Medication	Imbruvica™ (ibrutinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island
Issue Date	3/2014
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

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]

The National Cancer Comprehensive Network (NCCN) also recommends the use of Imbruvica for the B-cell lymphoma types: follicular (grade 1-2), gastric and nongastric MALT, diffuse large B-cell, AIDS-related B-cell, and post-transplant lymphoproliferative disorders. NCCN also recommends its use for primary CNS lymphoma and hairy cell leukemia.[2]

2. Coverage Criteria:

A. <u>B-Cell Lymphoma</u>

1. <u>Initial Authorization</u>

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

(1) **<u>Both</u>** of the following:

(a) Diagnosis of mantle cell lymphoma (MCL)

-AND-

(b) **<u>One</u>** of the following:

i. Patient has received at least one prior therapy for MCL
ii. Used in pre-treatment therapy in combination with Rituxan

(rituximab) to limit the number of cycles with RHyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen

-OR-

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

(a) Chronic Lymphocytic Leukemia (CLL)
(b) Small Lymphocytic Lymphoma (SLL)

-OR-

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

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

i. Follicular lymphoma (grade 1-2)
ii. Diffuse large B-cell lymphoma (non-GCB DLBCL and non-candidate for transplant)
iii. AIDS-related B-cell lymphoma
iv. Post-transplant lymphoproliferative disorders
v. Histologic transformation to diffuse large B-cell lymphoma
vi. Hairy cell leukemia
vii. Nodal or splenic marginal zone lymphoma (MZL)
viii. Gastric MALT lymphoma
ix. Nongastric MALT lymphoma
x. High grade B-cell lymphoma

-AND-

(b) Used as second-line or a subsequent therapy

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. 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.

D. Primary CNS Lymphoma

1. Initial Authorization

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

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

(a) Diagnosis of primary CNS lymphoma

-AND-

(b) **One** of the following;
i. Used as second-line or a subsequent therapy
ii. Used as induction therapy if patient is unsuitable or intolerant to high-dose methotrexate

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.

E. NCCN Recommended Regimens

1. Initial Authorization

a. **Imbruvica** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Imbruvica therapy

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. Imbruvica [package insert]. Sunnyvale, CA: Pharmacyclics, LLC. April 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 4, 2020.

Program	Prior Authorization - Imbruvica (ibrutinib)
Change Control	
3/2014	New Criteria
12/2014	Guideline updated with new indication Chronic Lymphocytic Leukemia with 17p deletion.
6/2015	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.
4/2016	Moved MCL, CLL and SLL criteria under the general diagnosis of NHL section Updated policy template
3/2017	Updated policy template. Added coverage for MZL. Updated background and references.
9/2017	Added new indication of chronic graft versus host disease. Updated background and references.

9/2018	Added coverage for B-Cell lymphoma types and CNS lymphoma. Added NCCN Recommended Regimen review criteria. Updated background and references.
9/2019	Updated criteria based on NCCN guidance. Updated references.
9/2020	Annual review. Updated lymphoma criteria based on NCCN guidelines. Updated references. Added Additional Clinical Rules section.