Commercial/Healthcare Exchange PA Criteria
Effective: November 2, 2016

Prior Authorization: Imbruvica

Products Affected: Imbruvica (ibrutinib) oral capsules, Imbruvica Oral Suspension

Medication Description:

IMBRUVICA is a kinase inhibitor indicated for the treatment of patients with:

- Mantle cell lymphoma (MCL) who have received at least one prior therapy. Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (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. Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.
- Chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.

Imbruvica is a small-molecule inhibitor of BTK. Imbruvica forms a covalent bond with a cysteine residue in the BTK active site, leading to inhibition of BTK enzymatic activity. BTK is a signaling molecule of the B-cell antigen receptor (BCR) and cytokine receptor pathways. BTK's role in signaling through the B-cell surface receptors results in activation of pathways necessary for B-cell trafficking, chemotaxis, and adhesion. Nonclinical studies show that Imbruvica inhibits malignant B-cell proliferation and survival in vivo as well as cell migration and substrate adhesion in vitro.

Covered Uses:

1. Mantle cell lymphoma
2. Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)
3. Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion
4. Waldenstrom's macroglobulinemia (WM)
5. Marginal zone lymphoma (MZL)
6. Chronic graft versus host disease (cGVHD)

Exclusion Criteria:
Imbruvica has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances:

1. Treatment naïve patients – Mantle Cell Lymphoma (MCL)

Required Medical Information:
1. Diagnosis
2. Previous therapies tried
3. Dose and frequency

Age Restrictions: None

Prescriber Restrictions: Prescribed by, or in consultation with, an Oncologist or a transplant specialist. (New starts only)

Coverage Duration:
Initial: 12 months
Continuation: 3 years

Other Criteria:

1. **Mantle cell lymphoma.** Approve if the patient meets the following criteria (a and b):
    a. Patient has a diagnosis of mantle cell lymphoma; AND
    b. Patient has received at least one prior therapy

2. **Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL).** Approve if the patient meets the following criteria (a or b):
    a. Patient has a diagnosis of chronic lymphocytic leukemia; OR
    b. Patient has a diagnosis of small lymphocytic lymphoma

3. **Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion**. Approve if the patient meets the following criteria (a or b):
    a. Patient has a diagnosis of chronic lymphocytic leukemia with 17p deletion
    b. Patient has a diagnosis of small lymphocytic lymphoma with 17p deletion

4. **Waldenström's macroglobulinemia (WM).** Approve if the patient meets the following criteria:
    a. Patient has a diagnosis of Waldenström's macroglobulinemia (WM)

5. **Marginal zone lymphoma (MZL).** Approve if the patient meets the following criteria:
    a. Patient has a diagnosis of Marginal zone lymphoma (MZL); **AND**
    b. Patient has received at least one prior anti-CD20-based therapy

6. **Chronic graft versus host disease (cGVHD).** Approve if the patient meets the following criteria:
    a. Patient has a diagnosis of Chronic graft versus host disease (cGVHD)
    b. Patient has received at least one or more lines of systemic therapy

For Imbruvica Suspension:

A. Patient must meet all clinical criteria above; **AND**
B. Patient must have tried and failed Imbruvica tablets or capsules **OR** be unable to swallow Imbruvica tablets or capsules

References:

1. Imbruvica [prescribing information]. New York, NY: Pfizer Labs; February 2016.
2. The NCCN Non-Hodgekin lymphoma Clinical Practice Guidelines in Oncology (Version 3.2016). © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 11, 2016
3. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 1.2017). © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 11, 2016

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/13/2016
2	Update	Addition of Prescriber Restriction	Prescriber Restriction	10/03/2018
3	Update	Updated Policy to match FDA Label (MZL and cGVHD); CCI removed Imbruvica from Oncology Policy and adopted EH criteria	All	5/1/2019
4	Update	Added continuation coverage duration of 3 years	Coverage Duration	7/1/2019
5	Update	Added Imbruvica Suspension to Products Affected and Other criteria	Products Affected, Other Criteria	10/31/2022
6	Update	For Marginal Zone Lymphoma; added “patient must have received at least one prior anti-CD20-based therapy” to criteria, was already in BL	Other Criteria	2/1/2023