MEDICAL MUTUAL®

Drug Policy

Policy:	Imbruvica (ibrutinib)	Annual Review Date: 02/18/2021 Last Revised Date: 02/18/2021

OVERVIEW

Imbruvica, a Bruton kinase inhibitor, is FDA indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy. Imbruvica is also FDA indicated for chronic lymphocytic leukemia (CLL) and small lymphocytic leukemia (SLL), 17p deletion CLL and SLL, treatment of patients with Waldenström's macroglobulinemia, Marginal Zone Lymphoma, and Chronic Graft Versus Host Disease. The National Comprehensive Cancer Network also supports use of Imbruvica for hairy cell leukemia and other B-cell lymphomas.

POLICY STATEMENT

This policy involves the use of Imbruvica. Prior authorization is recommended for pharmacy benefit coverage of Imbruvica. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Imbruvica as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Imbruvica be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Imbruvica is recommended in those who meet the following criteria:

1. **Mantle Cell Lymphoma**
   Criteria. *Approve if the patient has received at least one prior therapy for Mantle Cell Lymphoma*

2. **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**
   Criteria. *Approve*

3. **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

Criteria. *Approve*

4. **Chronic Graft-Versus-Host Disease (cGVHD)**
   Criteria. *Approve if the patient has tried and failed at least ONE prior therapy (e.g. methylprednisolone, prednisone, cyclosporine, tacrolimus, mycophenolate mofetil, imatinib) and Imbruvica will be used with systemic corticosteroids*

5. **Marginal Zone Lymphoma**
   Criteria. *Approve if the patient requires systemic therapy and has received at least one prior anti-CD20-based therapy (e.g. Rituxan), unless contraindicated.*

6. **B-cell Lymphomas (such as Follicular Lymphoma [grade 1-2], Gastric and Nongastric MALT Lymphoma, Histologic Transformation of Marginal Zone Lymphoma to Diffuse Large B-cell Lymphoma, Diffuse Large B-cell Lymphoma, High-Grade B-Cell Lymphoma, AIDS-Related B-cell Lymphoma, or Post-Transplant Lymphoproliferative Disorders)**
   Criteria. *Approve.*

7. **Hairy Cell Leukemia**
   Criteria. *Approve if Imbruvica is being used as a single agent for relapsed/refractory disease*

8. **Primary Central Nervous System (CNS) Lymphoma**
   Criteria. *Approve if the patient has relapsed or refractory disease*

9. **Another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**.
   Criteria. *Prescriber will provide specific diagnosis for documentation. Approve*

10. **Patient has been started on Imbruvica (continuation of therapy).**
    Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Imbruvica® capsules [prescribing information]. Sunnyvale, CA and Horsham, PA: Pharmacyclics and Janssen Biotech; January 2019.
2. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 11 February 2021. Search term: ibrutinib.
3. Ibrutinib. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 2 December 2020. Accessed on 11 February 2021.