SPECIALTY GUIDELINE MANAGEMENT

IMBRUVICA (ibrutinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

A. Mantle Cell Lymphoma (MCL)
Imbruvica is indicated for the treatment of patients with MCL who have received at least one prior therapy.

B. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Leukemia (SLL)
- Imbruvica is indicated for the treatment of patients with CLL/SLL
- Imbruvica is indicated for the treatment of patients with CLL/SLL with 17p deletion.

C. Waldenström's Macroglobulinemia (WM)
Imbruvica is indicated for the treatment of patients with WM.

D. Marginal Zone Lymphoma
Imbruvica is indicated for the treatment of patients with marginal zone lymphoma who require systemic therapy and have received at least one prior anti-CD20-based therapy

B. Compendial Use
Lymphoplasmacytic lymphoma (LPL), as a single agent:
1. As primary therapy
2. For previously treated disease that does not respond to primary therapy or for progressive or relapsed disease

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

A. Mantle Cell Lymphoma (MCL)
Authorization of 12 months may be granted for members with MCL who have received at least one prior therapy.

B. Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)
Authorization of 12 months may be granted for members with CLL/SLL.

C. Waldenström's Macroglobulinemia/lymphoplasmacytic lymphoma (WM/LPL)
Authorization of 12 months may be granted for members with WM/LPL.

D. Marginal Zone Lymphoma
Authorization of 12 months may be granted to members with marginal zone lymphoma who require systemic therapy and who have received at least one prior anti-CD20-based therapy.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Imbruvica [package insert]. Sunnyvale, CA: Pharmacyclics, Inc.; January 2017.
2. The NCCN Drugs & Biologics Compendium™ © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 20, 2017.