SPECIALTY GUIDELINE MANAGEMENT
IMBRUVICA (ibrutinib)

POLICY

A. 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.

FDA-Approved Indications
- Mantle Cell Lymphoma (MCL)
  - Imbruvica is indicated for the treatment of patients with MCL who have received at least one prior therapy.
- Chronic Lymphocytic Leukemia (CLL)
  - Imbruvica is indicated for the treatment of patients with CLL
  - Imbruvica is indicated for the treatment of patients with CLL with 17p deletion.
- Waldenström’s Macroglobulinemia (WM)
  - Imbruvica is indicated for the treatment of patients with WM.

Compendial Uses
- Lymphoplasmacytic lymphoma (LPL), as a single agent:
  - as primary therapy
  - for previously treated disease that does not respond to primary therapy or for progressive or relapsed disease
- Small lymphocytic lymphoma (SLL) (managed in the same manner as CLL)

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

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

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

3. Waldenström’s Macroglobulinemia/lymphoplasmacytic lymphoma (WM/LPL)
   Authorization of 12 months may be granted for members with WM/LPL who are prescribed Imbruvica as a single agent.

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

D. DOSAGE AND ADMINISTRATION
1. Dosing Limits
   The following dosing limits apply:
   - CLL/SLL: 420 mg per day
   - MCL: 560 mg per day
   - WM/LPL: 420 mg per day
REFERENCES