

zanubrutinib (BRUKINSA)

Diagnosis Considered for Coverage:

- Mantle cell lymphoma (MCL), following at least 1 prior therapy
- Waldenström's macroglobulinemia (WM)/ lymphoplasmacytic lymphoma
- Relapsed or refractory marginal zone lymphoma (MZL)
- Small Lymphocytic Lymphoma / Chronic Lymphocytic Leukemia
- Hairy Cell Leukemia

Coverage Criteria:

1. For diagnosis of mantle cell lymphoma (MCL):
 - Being used as single agent therapy, **and**
 - Being used for second-line or subsequent therapy, **and**
 - Dose does not exceed 320 mg per day.
2. For diagnosis of marginal zone lymphomas (e.g. Nodal Marginal Zone Lymphoma, Gastric MALT Lymphoma, Non-gastric MALT Lymphoma, Splenic Marginal Zone Lymphoma):
 - Being used as a single agent, **and**
 - Being used for second-line or subsequent therapy, **and**
 - Dose does not exceed 320 mg per day.
3. For diagnosis of Waldenström's macroglobulinemia (WM)/ lymphoplasmacytic lymphoma (LPL):
 - Being used as a single-agent therapy, **and**
 - Dose does not exceed 320 mg per day.

For Small Lymphocytic Lymphoma / Chronic Lymphocytic Leukemia:

- Being used as a single-agent therapy, **and**
- Dose does not exceed 320 mg per day.

4. For diagnosis of hairy cell leukemia:

- Being used as single agent therapy, **and**
- Disease progression despite treatment for relapsed or refractory disease, **and**
- Dose does not exceed 320 mg per day.

Coverage duration: one year

Effective Date: 02/28/2024