Reference number(s)
3411-A

SPECIALTY GUIDELINE MANAGEMENT

BRUKINSA (zanubrutinib)

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 Indication
Brukinsa is a kinase inhibitor indicated for the treatment of adult patients with:
1. Mantle cell lymphoma (MCL) who have received at least one prior therapy.
2. Waldenstrom's macroglobulinemia (WM).
3. Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.

B. Compendial Use
1. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
2. Gastric MALT Lymphoma/Non-gastric MALT Lymphoma
3. Nodal Marginal Zone Lymphoma
4. Splenic Marginal Zone Lymphoma
5. Waldenstrom Macroglobulinemia/Lymphoplasmacytic lymphoma

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Mantle Cell Lymphoma
Authorization of 12 months may be granted for treatment of mantle cell lymphoma as a single agent when the member has received at least one prior therapy.

B. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
Authorization of 12 months may be granted for treatment of CLL/SLL when used as a single agent.

C. Marginal Zone Lymphoma
Authorization of 12 months may be granted for treatment of marginal zone lymphoma, including gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma and splenic marginal zone lymphoma, when used as subsequent therapy for members who are intolerant or have contraindications to ibrutinib or for members who have received an anti-CD20 based-regimen (e.g., rituximab or obinutuzumab).

D. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma
Authorization of 12 months may be granted for treatment of Waldenstrom macroglobulinemia/Lymphoplasmacytic lymphoma when used as a single agent.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Brukinsa [package insert]. San Mateo, CA: BeiGene USA, Inc.; September 2021.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed January 20, 2022.