Reference number(s)
3411-A

Specialty Guideline Management
Brukinsa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Brukinsa	zanubrutinib

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[1]

Brukinsa is a kinase inhibitor indicated for the treatment of adult patients with:

- Mantle cell lymphoma (MCL) who have received at least one prior therapy.
- Waldenstrom's macroglobulinemia (WM).
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.
- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- Relapsed or refractory follicular lymphoma in combination with obinutuzumab, after two or more lines of systemic therapy.

Compendial Uses[2-4]

- Mantle Cell Lymphoma
- Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

- Gastric MALT Lymphoma (Extranodal Marginal Zone Lymphoma of the Stomach)/Non-gastric MALT Lymphoma (Extranodal Marginal Zone Lymphoma of Nongastric Sites)
- Nodal Marginal Zone Lymphoma
- Splenic Marginal Zone Lymphoma
- Waldenstrom Macroglobulinemia/Lymphoplasmacytic lymphoma/Bing-Neel Syndrome
- Hairy Cell Leukemia
- Follicular Lymphoma
- Primary CNS Lymphoma

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Test results confirming TP53 mutation, where applicable

Coverage Criteria

Mantle Cell Lymphoma[1-4]

Authorization of 12 months may be granted for treatment of mantle cell lymphoma when any of the following criteria are met:

- The requested medication will be used as a single agent when the member has received at least one prior therapy.
- The requested medication will be used as a component of TRIANGLE regimen for members with TP53 mutations for induction therapy.

  TRIANGLE regimen = alternating RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) + Brukinsa/RDHAP (rituximab, dexamethasone, and cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin) regimen
- The requested medication will be used in combination with rituximab for pre-treatment therapy or maintenance therapy.
- The requested medication will be used as induction therapy for TP53 mutated disease and in combination with Venclexta (venetoclax) and Gazyva (obinutuzumab)

Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)[1,2]

- Authorization of 12 months may be granted for treatment of CLL/SLL when used as a single agent.

- Authorization of 12 months may be granted for treatment of Histologic (Richter) transformation to diffuse large B-cell lymphoma in combination with tislelizumab.

Marginal Zone Lymphoma[1,2]

Authorization of 12 months may be granted for treatment of marginal zone lymphoma, including gastric MALT lymphoma (extranodal marginal zone lymphoma of the stomach), non-gastric MALT lymphoma (extranodal marginal zone lymphoma of nongastric sites), nodal marginal zone lymphoma and splenic marginal zone lymphoma, when used as subsequent therapy for members who have received an anti-CD20 based-regimen (e.g., rituximab or obinutuzumab).

Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma/Bing-Neel Syndrome[1,2]

Authorization of 12 months may be granted for treatment of Waldenstrom macroglobulinemia/Lymphoplasmacytic lymphoma when used as a single agent or for the treatment of Bing-Neel syndrome when used as a single agent or in combination with rituximab.

Hairy Cell Leukemia[2]

Authorization of 12 months may be granted for treatment of hairy cell leukemia when both of the following criteria are met:

- The member had disease progression after receiving therapy for relapsed or refractory disease.
- The requested medication will be used as a single agent.

Follicular Lymphoma[2]

Authorization of 12 months may be granted as third line and subsequent therapy in combination with obinutuzumab (Gazyva) for treatment of follicular lymphoma.

Primary CNS Lymphoma[2]

Authorization of 12 months may be granted as a single agent for treatment of relapsed or refractory disease.

Continuation of Therapy

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

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References

1. Brukinsa [package insert]. San Mateo, CA: BeiGene USA, Inc.; January 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 11, 2025.
3. Eskelund CW, Dahl C, Hansen JW, et al. TP53 mutations identify younger mantle cell lymphoma patients who do not benefit from intensive chemoimmunotherapy. Blood. 2017;130(17):1903-1910.
4. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology-Lymphoma. August 2023.