PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Brukinsa Prior Authorization Policy
- Brukinsa® (zanubrutinib capsules – BeiGene)

REVIEW DATE: 05/04/2022; selected revision 06/22/2022

OVERVIEW

Brukinsa, a Bruton's tyrosine kinase inhibitor (BTK), is indicated for the treatment of the following uses: [1]

- **Chronic lymphocytic leukemia or small lymphocytic lymphoma,** in adults.
- **Mantle cell lymphoma,** in adults who have received at least one prior therapy.
- **Marginal zone lymphoma**, relapsed or refractory, in adults who have received at least one anti-CD20-based regimen.
- **Waldenstrom's Macroglobulinemia,** in adults.

Guidelines

Brukinsa is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):[4]

- **B-Cell Lymphomas**: NCCN guidelines (version 5.2022 – July 12, 2022) address marginal zone lymphoma and mantle cell lymphoma.[2] The guidelines recommend Brukinsa as a preferred regimen among several as second-line and subsequent therapy (category 2A) for marginal zone lymphoma for patients who have relapsed/refractory disease after at least one prior anti-CD20 monoclonal antibody (mAB)-based regimen. There is a footnote which states to consider alternative Bruton tyrosine kinase inhibitors (Calquence® [acalabrutinib capsules] or Brukinsa) in patients with intolerance or contraindications to Imbruvica® (ibrutinib tablets or capsules) [category 2A]. For mantle cell lymphoma, Brukinsa is a preferred regimen for second-line or subsequent therapy (category 2A). There is a footnote that states that Brukinsa or Calquence has not been shown to be effective for Imbruvica-refractory mantle cell lymphoma with *BTK* C481S mutations. Patients with Imbruvica intolerance have been successfully treated with Brukinsa or Calquence without recurrence of symptoms.
- **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma:** NCCN guidelines (version 1.2023 – August 30, 2022) recommend single-agent Brukinsa as preferred first-line therapy for patients without 17p deletion/TP53 mutation (category 1) and with 17p deletion/TP53 mutation (category 2A). Brukinsa is also recommended as second-line and subsequent therapy for patients with or without 17p deletion/TP53 mutation (category 2A).[3] In the second-line and subsequent therapy setting, there is a footnote, which states that Brukinsa or Calquence have not been shown to be effective for Imbruvica-refractory chronic lymphocytic leukemia with BTK C481S mutations. Patients with Imbruvica intolerance have been successfully treated with Brukinsa or Calquence without recurrence of symptoms (category 2A).
- **Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma**: NCCN guidelines (version 1.2023 – July 6, 2022) recommend single-agent Brukinsa as a primary preferred therapy (category 1).[5] The guidelines also recommend Brukinsa as a preferred therapy option for previously treated disease (category 1). Brukinsa is also recommended for symptomatic management of Bing Neel Syndrome as a preferred regimen (category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Brukinsa. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Brukinsa is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Chronic Lymphocytic Leukemia.** Approve for 1 year if the patient is ≥ 18 years of age.

2. **Mantle Cell Lymphoma.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least one systemic regimen.
   Note: Examples of a systemic regimen contain one or more of the following products: rituximab, dexamethasone, cytarabine, carboplatin, cisplastin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, Velcade (bortezomib intravenous or subcutaneous injection), Revlimid (lenalidomide capsules), Imbruvica (ibrutinib capsules and tablets), or Calquence (acalabrutinib capsules).

3. **Marginal Zone Lymphoma**. Approve for 1 year if the patient meets the following criteria (A and B):
   Note: Marginal zone lymphoma includes gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least one systemic regimen.
   Note: Examples of a systemic regimen contain one or more of the following products: bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, Revlimid (lenalidomide capsules), Gazyva (obinutuzumab intravenous infusion) or Imbruvica (ibrutinib tablets and capsules).

4. **Small Lymphocytic Lymphoma.** Approve for 1 year if the patient is ≥ 18 years of age.

5. **Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma.** Approve for 1 year if the patient is ≥ 18 years of age.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Brukinsa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Brukinsa™ capsules [prescribing information]. San Mateo, CA: BeiGene; January 2023.
2. The NCCN B-Cell Lymphomas Guidelines in Oncology (version 5.2022 – July 12, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 20, 2023.
3. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2023 – August 30, 2022). © 2022 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on January 20, 2023.
4. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 27, 2022. Search term: zanubrutinib.

5. The NCCN Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2023 – July 6, 2022). © 2021 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on January 20, 2023.