PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/03/2020; selected revision 01/20/2021

OVERVIEW

Brukinsa, a Bruton's tyrosine kinase inhibitor (BTK), is indicated for the treatment of **mantle cell lymphoma,** in adults who have received at least one prior therapy.[1]

Disease Overview

Mantle cell lymphoma is a rare and fasting-growing type of non-Hodgkin lymphoma (NHL).[2,3] It accounts for approximately 3% of cases of newly diagnosed NHL. The condition is described as aggressive and non-curable. It is defined by the overexpression of cyclin D1. The median age at diagnosis is 68 years of age and it is more common in males. Mantle cell lymphoma is a cancer involving the lymphatic system which is part of the immune system comprised of lymph tissue, lymph nodes, the spleen, thymus, tonsils, and bone marrow. About 15% to 30% of patients have involvement of the gastrointestinal tract. Approximately one-third of patients with mantle cell lymphoma present with high levels of lactate dehydrogenase (LDH). Although there is no definitive standard of care, aggressive chemo-immunotherapy regimens containing rituximab and cytarbine are used for patients depending on fitness. Many targeted therapies are now available. Stem cell transplants is also an option.

Chronic lymphocytic leukemia (CLL) is one of the most prevalent adult leukemias in the Western world.[4] In 2019, an estimated 20,720 patients will be diagnosed with CLL in the US, and approximately 3,930 patients will die from the disease. The condition usually is diagnosed in older adults (≥ 70 years of age) and occurs more frequently in men. The leukemic cells appear as small, mature lymphocytes. CLL and small lymphocytic lymphoma (SLL) are different manifestations of the same condition and are managed similarly. In CLL, many of the abnormal lymphocytes are found in the blood, as well as in the bone marrow and lymphoid tissue. In SLL, there are few, if any, abnormal lymphocytes circulating in blood and most of the disease is in the lymph nodes, bone marrow, and other lymphoid tissue. The diagnosis requires the presence of at least 5 x 10^9/L monoclonal B-lymphocytes in the peripheral blood. SLL requires the presence of lymphadenopathy and/or splenomegaly with < 5 x 10^9/L B-lymphocytes found in the peripheral blood.

Guidelines

Several guidelines address use of Brukinsa.

- **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**:[4] The National Comprehensive Cancer Network (NCCN) guidelines for CLL/SLL (version 2.2021 – December 3, 2020) recommend Brukinsa as an option for second-line and subsequent therapy for patients without 17p deletion/TP53 mutation who are frail patients with significant comorbidity or patients < 65 years of age without significant comorbidities who have intolerance or contraindication to other BTK inhibitors (category 2A). For patients with 17p deletion/TP53 mutation, Brukinsa is recommended as a first-line therapy as an other recommended regimen for patients with a contraindication to other BTK inhibitors (category 2A). Also, for this population, Brukinsa is recommended as second-line and subsequent therapy as an other recommended regimen for patients with intolerance or a contraindication to other BTK inhibitors (category 2A).

- **Mantle Cell Lymphoma:**[2] The NCCN guidelines for B-cell lymphomas (version 4.2020 – August 13, 2020) address mantle tell lymphoma. Brukinsa is recommended as a preferred regimen among several as second-line therapy for patients with short response duration to prior chemoimmunotherapy, as well as for extended response duration prior to chemoimmunotherapy (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 the following criteria:

FDA-Approved Indication

1. **Mantle Cell Lymphoma.** Approve for 3 years if the patient has tried at least one prior therapy. Note: Example of therapies are Calquence® (acalabrutinib capsules); Imbruvica® (ibrutinib tablets and capsules) with or without a rituximab product; Revlimid® (lenalidomide capsules) with or without a rituximab product; Venclexta® (venetoclax tablets) with or without a rituximab product; RDHA (a rituximab product, dexamethasone, cytarabine) plus platinum (carboplatin, cisplatin, oxaliplatin); alternating RCHOP (a rituximab product, cyclophosphamide, doxorubin, vincristine, prednisone)/RDHAP (a rituximab product, dexamethasone, cytarbine, cisplatin); Treanda® (bendamustine injection) plus a rituximab product; RCHOP; NORDIC regimen (dose-intensified induction immunochemotherapy with ritixumab plus cyclophosphamide, vincristine, doxorubicin, prednisone [maxi-CHOP]) alternating with a rituximab product plus high-dose cytarbine); HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamathsone alternating with high-dose methotrexate and cytarabine plus rituximab); and VR-CAP (Velcade® [bortezomib injection for subcutaneous or intravenous use], a rituximab product, cyclophosphamide, doxorubicin, and prednisone).

Other Uses with Supportive Evidence

2. **Chronic Lymphocytic Leukemia.** Approve for 3 years if the patient has tried at least one prior therapy.
   Note: Example of therapies are Imbruvica® (ibrutinib tablets and capsules); Calquence® (acalabrutinib capsules); Copiktra® (duvelisib capsules); Gazyva® (obinutuzumab injection for intravenous use); Calquence with Gazyva; Venclexta® (venetoclax tablets) with Gazyva; Imbruvica with Gazyva; Venclexta with rituximab; Zydelig® (idelalisib tablets); and Zydelig plus rituximab.

3. **Small Lymphocytic Lymphoma.** Approve for 3 years if the patient has tried at least one prior therapy.
   Note: Example of therapies are Imbruvica® (ibrutinib tablets and capsules); Calquence® (acalabrutinib capsules); Copiktra® (duvelisib capsules); Gazyva® (obinutuzumab injection for intravenous use); Calquence with Gazyva; Venclexta® (venetoclax tablets) with Gazyva; Imbruvica with Gazyva; Venclexta with rituximab; Zydelig® (idelalisib tablets); and Zydelig plus rituximab.

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; November 2019.
2. The NCCN B-cell Lymphomas Guidelines in Oncology (version 4.2020 – August 13, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 17, 2021.
3. Maddocks K. Update on mantle cell lymphoma. *Blood*. 2018;132(16):1647-1656.
4. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 4.2021 – December 3, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at http://www.nccn.org. Accessed on January 17, 2021.