VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Brukinsa™ (zanubrutinib capsules – BeiGene)

DATE REVIEWED: 11/20/2019

OVERVIEW

Brukinsa, a kinase inhibitor, is indicated for the treatment of adults with mantle cell lymphoma who have received at least one prior therapy.[1] The indication was granted under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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 regiments containing rituximab and cytarbine are used for patients depending on fitness. Many targeted therapies are now available. Stem cell transplants is also an option.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for B-cell lymphomas (version 1.2020 – January 22, 2020) provide recommendations for patients with mantle cell lymphoma.[2] Various agents and chemotherapy regimens are recommended, many of which are given intravenously (IV) and involve rituximab-based therapies. For second-line therapy for patients with short response duration to prior chemoimmunotherapy preferred regimens include BTK inhibitors (Calquence® [acalabrutinib capsules]; Imbruvica® [ibrutinib capsules and tablets] with or without a rituximab product; and Brukinsa); Revlimid® (lenalidomide capsules) with or without a rituximab product; and Venclexta® (venetoclax tablets) [all 2A recommendations]. For second-line therapy for extended response duration prior to chemoimmunotherapy, preferred regimens include BTK inhibitors (Calquence; Imbruvica with or without a rituximab product; and Brukinsa), Revlimid with or without a rituximab product; Treanda® (bendamustine injection for intravenous use) with or without a rituximab product (if not previously given); and Velcade® (bortezomib injection for intravenous or subcutaneous use) with or without rituximab (all 2A recommendations).

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Brukinsa.

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® (acalbrutinib 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).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Brukinsa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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 1.2020 – January 22, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 28, 2020.
3. Maddocks K. Update on mantle cell lymphoma. *Blood*. 2018;132(16):1647-1656.

HISTORY

Type of Revision	Summary of Changes*	Date Reviewed
New policy	---	11/20/2019
Update	12/2/2019: No criteria changes. Overview changed to include updated National Comprehensive Cancer Network guidelines for B-Cell Lymphomas.	--
Update	12/22/2020: No criteria changes. Overview changed to include updated National Comprehensive Cancer Network guidelines for B-Cell Lymphomas	--