



Commercial & Healthcare Exchange PA Criteria
Effective: December 20th, 2019

Prior Authorization: Brukinsa

Products Affected: Brukinsa (zanubrutinib) oral capsule

Medication Description: Zanubrutinib is a Bruton tyrosine kinase (BTK) inhibitor approved for the treatment of adult patients with mantle cell lymphoma who have received at least 1 prior therapy. Zanutrutinib is a second generation Bruton tyrosine kinase (BTK) inhibitor. BTK is a signaling molecule early within the B-cell antigen receptor (BCR) signaling cascade. Signaling from BCR regulates several pro-survival mechanisms of B-cells, including proliferation, trafficking, chemotaxis, and adhesion. Zanutrutinib forms a covalent bond with a cysteine residue in the BTK active site leading to inhibition of BTK enzymatic activity, inhibition of malignant B-cell proliferation, and reduced tumor growth.

Covered Uses: Treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Previous therapies tried/failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist

Coverage Duration: 12 Months

Other Criteria:

- A. Patient has a diagnosis of Mantle Cell Lymphoma; AND
- B. Patient must have received at least one prior therapy for mantle cell lymphoma

References:

1. Product Information: BRUKINSA(TM) oral capsules, zanubrutinib oral capsules. BeiGene USA Inc (per FDA), San Mateo, CA, 2019.



Policy Revision history

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|--------------|-----------------------|--------------------------|--------------------------|-------------|
| 1 | New Policy | New Policy | All | 12.5.19 |

