

Zanubrutinib capsule (BRUKINSA)

Criteria for Use

December 2024

VA Pharmacy Benefits Management Services and the National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERNET](#) or [PBM INTRANET](#) site for further information.

Exclusion Criteria *If the answer to ANY item below is met, the patient should NOT receive zanubrutinib*

- Patient has not been screened for Hepatitis B Virus (HBV).
- Unmanageable drug-drug or drug-food interaction identified
- History of stroke or intracranial hemorrhage in prior 6 months
- Clinically significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, congestive heart failure (NYHA Class 3 or 4), or myocardial infarction in prior 6 months
- Current or history of Central Nervous System (CNS) lymphoma
- Active or uncontrolled infection
- Known pregnancy
- Lactating

Inclusion Criteria *One of the following indications must be met:*

- Relapsed or refractory mantle cell lymphoma and progressive disease or intolerance to at least one prior therapy
- Relapsed or refractory marginal zone lymphoma and received at least one anti-CD20-based regimen
- Waldenstrom macroglobulinemia
- Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL) if acalabrutinib is not clinically appropriate for patient
- Relapsed or refractory follicular lymphoma, in combination with obinutuzumab, after two or more lines of therapy

Additional Inclusion Criteria *All must be fulfilled to meet criteria:*

- Care provided by a VA/VA Community Care hematology/oncology provider
- Goals of care and role of Palliative Care consult have been discussed and documented
- Eastern Cooperative Oncology Group Performance Status 0-2

Additional Inclusion Criteria *Select if applicable:*

- For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs. benefits of treatment and the use of effective contraception during therapy and for 1 week after the last dose
- Advise patients not to breastfeed/provide breastmilk during treatment and for at least 2 weeks after the last dose

Other Justification