Ibrutinib (IMBRUVICA)
Criteria for Use
December 2024

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

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 INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive ibrutinib.

- ☐ Patient has not been screened for Hepatitis B Virus (HBV)
- ☐ Unmanageable drug-drug or drug-food interaction
- ☐ Active or uncontrolled infection
- ☐ 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
- ☐ Severe hepatic impairment (Child-Pugh C) or total bilirubin > 3x Upper Limit of Normal (unless non-hepatic origin or Gilbert syndrome)
- ☐ Known pregnancy
- ☐ Lactating

Inclusion Criteria

One of the following criteria must be met.

- ☐ Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL) if acalabrutinib is not clinically appropriate for patient
- ☐ Waldenstrom Macroglobulinemia
- ☐ Previously treated chronic Graft versus Host Disease (cGVHD) after Hematopoietic Stem Cell Transplant

Additional Inclusion Criteria

All of the following criteria must be met.

- ☐ Care for the oncologic condition provided by VA or VA Community Care 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 month after stopping treatment
- ☐ Advise patients not to breastfeed/provide breastmilk during treatment and for 1 week after last dose

Other Justification

- ☐

September 2014, March 2016, September 2018, April 2019, September 2019, June 2023, June 2024, Dec 2024
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