Idelalisib (Zydelig®)

Criteria for Use

April 2022

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 UTILIZE 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 www.pbm.va.gov or http://vaww.pbm.va.gov for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive idelalisib:

☐ Unable to swallow oral capsules whole and intact

☐ Patient with history of non-adherence with oral medication, follow-up appointments or laboratory visits

☐ Unmanageable drug interaction identified

☐ History of serious allergic reactions including anaphylaxis and toxic epidermal necrolysis

☐ Gastrointestinal condition that may interfere with absorption

☐ Chronic or unresolved infection

☐ Severe renal impairment defined as CrCl $\leq$ 15 ml/min (drug has not been studied in this setting)

☐ AST (SGOT) or ALT (SGPT) $\geq$ 2.5x ULN, bilirubin > 1.5x ULN, or with moderate-severe hepatic impairment (Child-Pugh B or C)

☐ Absolute Neutrophil Count (ANC) < 1000 cells/µL, and/or platelet count < 50,000 cells/µL unless bone marrow involvement

☐ Pregnancy (known pregnancy or positive pregnancy test)

☐ Breastfeeding

Inclusion Criteria

All of the following must be fulfilled to meet criteria:

☐ Care provided by VA or VA Community Care hematology/oncology provider

☐ Goals of care and role of Palliative Care consult have been discussed and documented

☐ Eastern Cooperative Oncology Group (ECOG) Performance Status 0 – 2

AND the following indication:

☐ Relapsed Chronic Lymphocytic Leukemia (CLL) with rituximab (if rituximab alone is appropriate due to comorbidities)

For patient of childbearing potential

□ Pregnancy should be excluded prior to receiving idelalisib and the patient provided contraceptive counseling on potential risk vs. benefit of taking idelalisib if patient were to become pregnant; effective contraception should be used during treatment and for 1 month after the last dose; partners should use effective contraception for 3 months after last dose