

Selinexor (XPOVIO)

Criteria for Use

November 2021

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 INTERnet](#) or [PBM INTRANet](#) site for further information.

Exclusion Criteria

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

- Inability to reliably take drug according to prescribed schedule
- Malabsorption syndrome or other condition affecting oral absorption
- Patient is not a candidate for dexamethasone therapy
- Active CNS disease
- Active, unstable cardiovascular function
- Ongoing or active systemic infection including hepatitis B or C, or known HIV
- ANC < 1000/mm³
- Platelet count < 75,000/mm³ (< 50,000/mm³ if myeloma involvement in bone marrow ≥ 50%)
- Hemoglobin < 8 g/dL; Must transfuse to hemoglobin above 8 g/dL prior to initiation
- Total bilirubin ≥ 2 x ULN (Gilbert's syndrome ≥ 3 x ULN) and AST and ALT ≥ 2.5x ULN
- Estimated creatinine clearance < 15 ml/min
- Sodium level ≤ 130 mmol/L
- Patient with evidence of anorexia and/or dehydration
- Concomitant therapy with antiplatelet drugs
- Unable to take antiemetic prophylaxis & breakthrough regimen for highly emetogenic therapy
- Pregnancy
- Breastfeeding

Inclusion Criteria

Treatment for one of the following indications, per FDA labeling, must apply to meet criteria:

- In combination with bortezomib and dexamethasone to treat multiple myeloma, after at least one prior line of therapy
- In combination with dexamethasone to treat relapsed or refractory multiple myeloma after at least 4 prior myeloma therapies (unless contraindicated or patient is unable to tolerate) and whose disease is refractory to the following:
 - at least 2 proteasome inhibitors (i.e. bortezomib, carfilzomib),
 - and at least 2 immunomodulatory agents (i.e. lenalidomide, pomalidomide),
 - and an anti-CD38 monoclonal antibody (i.e. daratumumab)
- Relapsed or refractory Diffuse Large B-cell lymphoma, after at least 2 prior lines of therapy

Additional Inclusion Criteria

- Care is provided by a VA/VA Community Care hematology/oncology provider
- Goals of care and role of Palliative Care consult have been discussed and documented
- ECOG performance status ≤ 2
- Patients of child-bearing potential and patients with partners of child-bearing potential: counseling provided on potential risk vs. benefit of taking drug if patient were to become pregnant. Continue effective contraception until 1 week after last dose.