

Generic Name: Selinexor**Therapeutic Class or Brand Name:** Xpovio®**Applicable Drugs (if Therapeutic Class):**
Antineoplastic**Preferred:** N/A**Non-preferred:** N/A**Date of Origin:** 8/5/2019**Date Last Reviewed / Revised:** 10/14/2022

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - IV are met)

- I. Documented diagnosis of one of the following conditions A, B, or C and must meet criteria listed under applicable diagnosis:
 - A. Multiple Myeloma**
 1. Member has received at least one prior therapy.
 2. Used in combination with bortezomib and dexamethasone.
 - B. Relapsed or Refractory Multiple Myeloma**
 1. Member has received at least four prior therapies.
 2. Disease is refractory to at least two proteasome inhibitors (bortezomib, carfilzomib, ixazomib), at least two immunomodulatory agents (thalidomide, lenalidomide, pomalidomide), and an anti-CD38 monoclonal antibody (such as daratumumab).
 3. Used in combination with dexamethasone.
 - C. Diffuse Large B-Cell Lymphoma (DLBCL)**
 1. Adult patients with a documented diagnosis of relapse or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma.
 2. Member has received at least two prior lines of systemic therapy.
 3. Used as monotherapy.
- II. Verify patient's pregnancy potential prior to initiating Selinexor.
- III. Age 18 years old or older.
- IV. Prescribed by or in consultation with an oncologist.

EXCLUSION CRITERIA

- None.

OTHER CRITERIA

- Thrombocytopenia: Monitor platelet counts throughout treatment. Manage with dose interruption and/or reduction and supportive care.
- Neutropenia: Monitor neutrophil counts throughout treatment. Manage with dose interruption and/or reduction and granulocyte colony-stimulating factors.
- Hyponatremia: Monitor serum sodium levels throughout treatment. Correct for concurrent hyperglycemia and high serum paraprotein levels. Manage with dose interruption, reduction, or discontinuation, and supportive care.
- Serious infection: Monitor for infection and treat promptly.
- Cataract: Cataracts may develop or progress. Treatment of cataracts usually requires surgical removal of the cataract.
- Gastrointestinal toxicity: Provide antiemetic prophylaxis. Manage with dose interruption and/or reduction, antiemetics, and supportive care.
- Neurological Toxicity: Advise patients to refrain from driving and engaging in hazardous occupations or activities until neurological toxicity resolves. Optimize hydration status and concomitant medications to avoid dizziness or mental status changes.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential and males with a female partner of reproductive potential, of the potential risk to a fetus and use of effective contraception.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 20 mg, 40 mg, 50mg, 60mg tablets: (30 Day Supply)
 - Multiple myeloma:
 - In Combination with Bortezomib and Dexamethasone (XVd):
 - 100mg orally once weekly on Day 1 of each week (4 tablets / 28 days)
 - In combination with Dexamethasone:
 - 80 mg orally on Days 1 and 3 of each week (8 tablets / 28 days)
 - Diffuse large B-cell lymphoma:
 - 60 mg orally on Days 1 and 3 of each week (8 tablets / 28 days)

APPROVAL LENGTH

- **Authorization**: 6 months.
- **Re-authorization**: 6 months, an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. Jagannath S, Vogl D, Dimopoulos M et al. Phase 2b Results of the STORM Study: Oral Selinexor plus Low Dose Dexamethasone (Sd) in Patients with Penta-Refractory Myeloma (penta-MM). *Clinical Lymphoma Myeloma and Leukemia*. 2018;18:S249-S250. doi:10.1016/j.clml.2018.07.149.
2. Xpovio®. Prescribing Information. Karyopharm Therapeutics Inc. July 2022. Accessed October, 14, 2022. <https://www.karyopharm.com/wp-content/uploads/2019/07/NDA-212306-SN-0071-Prescribing-Information-01July2019.pdf>.
3. NCCN Guideline Version 1.2023 – Multiple Myeloma:
https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf
4. NCCN Guideline Version 5.2022 – B-Cell Lymphomas:
https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.