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: 11/18/2024

PRIOR AUTHORIZATION CRITERIA

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

I. Documentation of one of the following diagnoses A through C AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Multiple Myeloma
   i. Documented disease progression on at least one prior therapy.
   ii. Xpovio will be used in combination with bortezomib and dexamethasone.

B. Relapse or Refractory Multiple Myeloma
   i. Documented intolerance or disease progression on at least four prior therapies.
   ii. Disease is refractory to at least two proteasome inhibitors [eg, bortezomib, Kyprolis (carfilzomib), ixazomib (Ninlaro)], at least two immunomodulatory agents [eg, Thalomid (thalidomide), lenalidomide, Pomalyst (pomalidomide)], and an anti-CD38 monoclonal antibody [eg, Darzalex (daratumumab), Sarclisa (isatuximab)].
   iii. Xpovio will be used in combination with dexamethasone.

C. Diffuse Large B-Cell Lymphoma (DLBCL)
   i. Documentation of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma.
   ii. Documentation of disease progression on at least two prior lines of systemic therapy.
   iii. Xpovio will be used as monotherapy.

II. Minimum Age Requirement: 18 years old

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Multiple myeloma:
  - 50 mg tablets: 8 tablets per 28 days
- Relapsed or Refractory Multiple Myeloma
  - 40 mg tablets: 32 tablets per 28 days
- Diffuse large B-cell lymphoma:
  - 60 mg tablets: 8 tablets per 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 does not show evidence of progressive disease.

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., 2022. Accessed October 25, 2024. Available at: www.accessdata.fda.gov/drugsatfda_docs/label/2022/212306s011lbl.pdf
3. National Comprehensive Cancer Network (NCCN). Multiple Myeloma. Version 1.2025, September 17, 2024. Accessed October 25, 2024. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf

4. National Comprehensive Cancer Network (NCCN). B-Cell Lymphomas. Version 3.2024, August 26, 2024. Accessed October 25, 2024. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf