

Xpovio (selinexor)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Xpovio (selinexor)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Xpovio (selinexor) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsed or refractory Diffuse Large B-cell Lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, high-grade B-cell lymphoma, HIV related B-cell lymphoma, or monomorphic post-transplant lymphoproliferative disorder (b-cell type) (Label, NCCN 2A) **AND**
 - A. Individual previously received at least two prior lines of systemic therapy; **AND**
 - B. Individual is using as monotherapy;

OR

- II. Individual has a diagnosis of relapsed or refractory Multiple Myeloma; **AND**
 - A. Individual is using in combination with dexamethasone; **AND**
 - B. Individual previously received at least four prior lines of therapies; **AND**
 - C. Disease is refractory to all of the following:
 - 1. At least two proteasome inhibitors (for example, bortezomib, carfilzomib, or ixazomib); **AND**
 - 2. At least two immunomodulatory agents (for example, lenalidomide, pomalidomide, or thalidomide); **AND**
 - 3. An anti-CD38 monoclonal antibody (for example, daratumumab);

OR

- III. Individual has a diagnosis of relapsed or progressive Multiple Myeloma; **AND**
 - A. Individual is using as subsequent therapy; **AND**
 - B. Individual is using in combination with bortezomib and dexamethasone; **OR**
 - C. Individual is using in combination with dexamethasone and daratumumab (Darzalex or Darzalex Faspro) (NCCN 2A); **OR**
 - D. Individual is in combination with carfilzomib (Kyprolis) and dexamethasone (NCCN 2A); **OR**
 - E. Individual is using in combination with pomalidomide and dexamethasone after receiving two prior therapies that included an immunomodulatory agent and proteasome inhibitor (NCCN 2A).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed: March 4, 2024.
 - a. B-Cell Lymphomas. V1.2024. Revised January 18, 2024.
 - b. Multiple Myeloma. V3.2024. Revised March 8, 2024.
6. NCT02227251. U.S. National Library of Medicine, ClinicalTrials.gov website. Available at <https://clinicaltrials.gov/ct2/show/NCT02227251?term=nct02227251&draw=2&rank=1>.
7. NCT02336815. U.S. National Library of Medicine, ClinicalTrials.gov website. Available at <https://clinicaltrials.gov/ct2/show/NCT02336815?term=nct02336815&rank=1>.
8. Vogl DT, Dingli D, Cornell RF, et al. Selective inhibition of nuclear export with oral selinexor for treatment of relapsed or refractory multiple myeloma. J Clin Onc 2018 Mar;36(9):859-866.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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