

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Xpovio Prior Authorization Policy

- Xpovio® (selinexor tablets – Karyopharm Therapeutics)

REVIEW DATE: 03/06/2024

OVERVIEW

Xpovio, a nuclear export inhibitor, is indicated for treatment of the following conditions:¹

- **Diffuse large B-cell lymphoma (DLBCL)**, not otherwise specified (including DLBCL arising from follicular lymphoma), for treatment of relapsed or refractory disease in adults, after at least two lines of systemic therapy.
- **Multiple myeloma:**
 - In combination with dexamethasone for treatment of relapsed or refractory disease in adults who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.
 - In combination with bortezomib and dexamethasone, in adults who have received at least one prior therapy.

For DLBCL, Xpovio was approved under accelerated approval based on response rate. Continued approval may be contingent upon verification in a confirmatory trial(s).

Guidelines

Xpovio is addressed in the following guidelines from the National Comprehensive Cancer Network (NCCN):

- **B-Cell Lymphoma:** NCCN guidelines (version 1.2024 – January 18, 2024) recommend Xpovio as third-line and subsequent therapy (category 2A) for DLBCL (including for histologic transformation of indolent lymphomas to DLBCL), after at least two lines of systemic therapy.³ This includes patients with disease progression after transplant or chimeric antigen receptor T-cell therapy.
- **Multiple Myeloma:** NCCN guidelines (version 2.2024 – November 1, 2023) recommend various regimens as primary therapy (transplant eligible and non-transplant candidates), maintenance therapy, and for previously treated multiple myeloma.² Xpovio/bortezomib/dexamethasone (once weekly) [category 1] is recommended as one of the “Preferred Regimens” for lenalidomide-refractory disease following one to three previous therapies. Xpovio/dexamethasone (category 2A) after at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody, is recommended for patients with late relapses (> three prior therapies). Xpovio/Darzalex® (daratumumab injection)/dexamethasone, Xpovio/Kyprolis® (carfilzomib intravenous infusion)/dexamethasone, and Xpovio/Pomalyst® (pomalidomide capsules)/dexamethasone are among the regimens (all category 2A) considered “Useful in Certain Circumstances” for previously treated multiple myeloma, for early relapses (one to three prior therapies).

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POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Xpovio. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xpovio is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Diffuse Large B-Cell Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):

Note: This includes patients with histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma.

A) Patient is ≥ 18 years of age; AND

B) Patient has been treated with at least two prior systemic therapies.

2. **Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) The medication will be taken in combination with dexamethasone; AND

C) Patient meets one of the following (i, ii, or iii):

i. Patient has tried at least four prior regimens for multiple myeloma; OR

ii. Patient meets both of the following (a and b):

a) Patient has tried at least one prior regimen for multiple myeloma; AND

b) The medication will be taken in combination with bortezomib; OR

iii. Patient meets both of the following (a and b):

a) Patient has tried at least one prior regimen for multiple myeloma; AND

Note: Examples of prior regimens include bortezomib/Revlimid (lenalidomide capsules)/dexamethasone, Kyprolis (carfilzomib intravenous infusion)/Revlimid/dexamethasone, Darzalex (daratumumab intravenous infusion)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody.

b) The medication will be taken in combination with Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Kyprolis (carfilzomib intravenous infusion), or Pomalyst (pomalidomide capsules).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Xpovio is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Xpovio® tablets [prescribing information]. Newton, MA: Karyopharm Therapeutics; July 2022.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 2.2024 – November 1, 2023). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 4, 2024.
3. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2024 – January 18, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 4, 2024.

