PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Xpovio Prior Authorization Policy
- Xpovio™ (selinexor tablets – Karyopharm Therapeutics)

REVIEW DATE: 02/03/2021

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 adults with relapsed or refractory disease, after at least two lines of systemic therapy.
- **Multiple myeloma**:
  - In combination with dexamethasone for adults with relapsed or refractory disease who have received at least four prior therapies and whose disease is refractory to at least two proteasomes 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 both of these indications, Xpovio was approved under accelerated approval based on response rate. Continued approval may be contingent upon verification in a confirmatory trial.

Guidelines

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

- **B-Cell Lymphoma:** NCCN guidelines (version 1.2021 – January 20, 2021) recommend Xpovio as third-line and subsequent therapy of DLBCL, after at least two lines of systemic therapy.[3]
- **Multiple Myeloma:** NCCN guidelines (version 4.2021 – December 10, 2020) recommend various regimens as primary therapy (transplant eligible and non-transplant candidates), maintenance therapy, and previously treated multiple myeloma.[2] Xpovio/bortezomib/dexamethasone is among the other recommended regimens for previously treated disease. Xpovio/dexamethasone (specifically for the approved indication), Xpovio/Darzalex (daratumumab injection)/dexamethasone, and Xpovio/Pomalyst (pomalidomide capsules)/dexamethasone are among the regimens considered useful in certain circumstances for previously treated multiple myeloma.

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 the following criteria:

FDA-Approved Indications

1. **Diffuse Large B-Cell Lymphoma.** Approve for 3 years if the patient meets BOTH of the following (A and B):
   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 3 years 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
         b) The medication will be taken in combination with Darzalex (daratumumb infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules).

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

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 [prescribing information]. Newton, MA: Karyopharm Therapeutics; December 2020.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 4.2021 – December 10, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 31, 2021.
3. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2021 – January 20, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 31, 2021.