

Clinical Pharmacy Program Guidelines for Xpovio

Program	Prior Authorization
Medication	Xpovio™ (selinexor)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	10/2019
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

1. Background:

Xpovio (selinexor) is a nuclear export inhibitor indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) 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. Xpovio is also indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

2. Coverage Criteria:

<p>A. <u>Multiple Myeloma</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Xpovio will be approved based on all of the following:</p> <p>(1) Diagnosis of relapsed or refractory multiple myeloma (RRMM)</p> <p style="text-align: center;">-AND-</p> <p>(2) Patient has received at least four prior therapies</p> <p style="text-align: center;">-AND-</p> <p>(3) Disease is refractory to all of the following:</p>

- (a) Two proteasome inhibitors
- (b) Two immunomodulatory agents
- (c) An anti-CD38 monoclonal antibody

-AND-

- (4) Used in combination with dexamethasone

Authorization will be issued for 12 months.

2. Reauthorization

- a. Xpovio** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Xpovio therapy

Authorization will be issued for 12 months.

B. Diffuse Large B-cell Lymphoma (DLBCL)

1. Initial Authorization

- a. Xpovio** will be approved based on **both** of the following:

- (1) Diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL)) (including DLBCL arising from follicular lymphoma)

-AND-

- (2) Patient has received at least 2 lines of systemic therapies

Authorization will be issued for 12 months.

2. Reauthorization

- a. Xpovio** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Xpovio therapy

Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Xpovio** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Xpovio** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Xpovio therapy.

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Xpovio [package insert]. Newton, MA: Karyopharm Therapeutics Inc.; June 2020.

Program	Prior Authorization
Change Control	
Date	Change
10/2019	New program
01/2021	Annual review. Updated background and criteria with new indication of DLBCL. Updated reference. Added Additional Clinical Rules section.