Clinical Policy Title:	selinexor
Policy Number:	RxA.568
Drug(s) Applied:	Xpovio®
Original Policy Date:	03/06/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Multiple Myeloma (MM) (must meet all)**:**

1. Diagnosis of MM;
2. Request meets one of the following (a, b, c or d):
   a. Prescribed in combination with bortezomib and dexamethasone;
   b. Prescribed in combination with Darzalex® and dexamethasone;
   c. Prescribed in combination with Pomalyst® and dexamethasone and member has received at least two prior therapies including an immunomodulatory agent and a proteasome inhibitor;
   d. Member has received ≥ 4 prior lines of therapy that include all of the following (i, ii, and iii):
      i. Two proteasome inhibitors (e.g., bortezomib, Kyprolis®, Ninlaro®);
      ii. Two immunomodulatory agents (e.g., Revlimid®, Pomalyst®, Thalomid®);
      iii. One anti-CD38 monoclonal antibody (e.g., Darzalex®).

Approval Duration
All Lines of Business (except Medicare): 6 months

B. Diffuse Large B-Cell Lymphoma (DLBCL) (must meet all)**:**

1. Diagnosis of DLBCL and transformed DLBCL arising from follicular lymphoma;
2. Treatment of histologic transformation to diffuse large B-cell lymphoma in patients who have received multiple prior therapies including ≥ 2 lines of chemoimmunotherapy for indolent or transformed disease;
3. Third line and subsequent therapy (only after at least 2 lines of systemic therapy) for partial response, no response, relapsed, progressive, or refractory disease.

Approval Duration
All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Multiple Myeloma Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. B-cell lymphoma Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title was updated as “selinexor”. 2. Line of business policy applies to all lines of business. 3. Initial approval criteria updated with “Diffuse Large B-Cell Lymphoma info. added”. 4. Continued therapy approval criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance.” 5. References were reviewed and updated.	09/30/2020	12/07/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.4.a, I.A.4.b and I.A.4.c were updated to include combination therapies. 2. Initial Approval Criteria I.A.5.a was updated to include maximum dose criteria. 3. Continued Therapy Approval II.A.3.a was updated to include maximum dose criteria. 4. References were reviewed and updated.	10/09/2021	12/07/2021
Policy was reviewed: 1. References were reviewed and updated.	07/27/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	8/28/2024	9/13/2024