Clinical Policy Title:	selinexor
Policy Number:	RxA.568
Drug(s) Applied:	Xpovio®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of RRMM;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Age ≥ 18 years;
4. 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®);
5. Request meets one of the following (a or b)*:
   a. Dose does not exceed one of the following (i or ii):
      i. Prescribed in combination with bortezomib and dexamethasone: 100 mg per week;
      ii. All other combination regimens: 160 mg per week;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

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

1. Diagnosis of diffuse large B-cell lymphoma (DLBCL) and transformed DLBCL arising from follicular lymphoma;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Age ≥ 18 years;
4. 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;

5. Third line and subsequent therapy (only after at least 2 lines of systemic therapy) for partial response, no response, relapsed, progressive, or refractory disease;
6. Request meets one of the following (a or b)*:
   a. Dose does not exceed 120 mg per week;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria for the covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. For RRMM: New dose does not exceed one of the following (i or ii):
      i. Prescribed in combination with bortezomib and dexamethasone: 100 mg (5 tablets) per week;
      ii. All other combination regimens: 160 mg per week;
   b. For DLBCL: New dose does not exceed 120 mg per week;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network. Multiple Myeloma Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed July 27, 2022.
2. National Comprehensive Cancer Network. B-cell lymphoma Version 5.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 27, 2022.

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	09/30/2020	12/07/2020

medication that has been authorized by RxAdvance." 5. References were reviewed and updated.		
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