RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	ixazomib
Policy Number:	RxA.418
Drug(s) Applied:	Ninlaro®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Ixazomib (Ninlaro®) is a proteasome inhibitor. It is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Ixazomib (Ninlaro®)	MM	4 mg PO on Days 1, 8, and 15 of a 28-day cycle	4 mg/week

Dosage Forms

- Capsules: 2.3 mg, 3 mg, 4 mg.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of MM;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Prescribed in combination with dexamethasone with or without either Revlimid or Pomalyst;
   **Prior authorization is required for Revlimid and Pomalyst.*
5. Request meets one of the following (a or b):
   a. Dose does not exceed 4 mg (1 tablet) per week for 3 weeks of a 28-day (4-week) treatment cycle;
   b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

HIM: 6 months

B. Systemic Light Chain Amyloidosis (off-label) (must meet all):
1. Diagnosis of relapsed or refractory systemic light chain amyloidosis;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval Duration
Commercial: 6 months
Medicaid: 6 months
HIM: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):
1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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. New dose does not exceed 4 mg (1 tablet) per week for 3 weeks of a 28-day (4- week) treatment cycle;
    b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

Approval Duration
Commercial: 6 months
Medicaid: 6 months
HIM: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MM: multiple myeloma

APPENDIX B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Pomalyst® (pomalidomide)	Varies	Varies
Revlimid® (lenalidomide)	Varies	Varies
dexamethasone	Varies	Varies

Therapeutic alternatives are listed as Brand name®(generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Not applicable

References

1. Ninlaro Prescribing Information. Cambridge, MA: Millennium Pharmaceuticals, Inc.; February 2020. Available at https://www.ninlaro.com/prescribing-information.pdf . Accessed July 22, 2020.
2. National Comprehensive Cancer Network Drug and Biologics Compendium. Available at www.nccn.org . Accessed July 22, 2020.
3. National Comprehensive Cancer Network. Multiple Myeloma version 4.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf Accessed July 22, 2020.
4. National Comprehensive Cancer Network. Systemic Light Chain Amyloidosis version 1.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/amyloidosis.pdf . Accessed July 22, 2020.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed July 22, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Initial and Continued approval duration was updated to include Medicaid, Commercial & HIM approval duration. 4. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 5. References were reviewed and updated.	7/22/2020	9/14/2020