Clinical Policy: Ixazomib (Ninlaro)

Reference Number: ERX.SPA.240
Effective Date: 09.01.18
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Ixazomib (Ninlaro®) is a proteasome inhibitor.

FDA Approved Indication(s)
Ninlaro 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.

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Ninlaro is **medically necessary** when the following criteria are met:

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 one of the following ways (a, b, or c):
   a. Subsequent therapy as a single agent for transplant candidates;
   b. As a single agent after prior autologous stem cell transplant;
   c. In combination with dexamethasone with or without either Revlimid®, Pomalyst®, or cyclophosphamide;*

   **Prior authorization may be required for Revlimid, Pomalyst, or cyclophosphamide.*
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. 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 – Length of Benefit
Medicaid – 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*).*

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

Approval duration:

Commercial – Length of Benefit
Medicaid – 6 months

C. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma (off-label) (must meet all)**:**
1. Diagnosis of Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Prescribed in combination with Rituxan®* and dexamethasone;
   **Prior authorization may be required for Rituxan.*
5. 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*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

D. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Ninlaro for a 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. 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)*.*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MM: multiple myeloma
NCCN: National Comprehensive Cancer Center

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MM	4 mg PO on Days 1, 8, and 15 of a 28-day cycle See Ninlaro Prescription Information for Revlimid and dexamethasone dosing.	4 mg/week

VI. Product Availability

Capsules: 2.3 mg, 3 mg, 4 mg

VII. References

1. Ninlaro Prescribing Information. Cambridge, MA: Millennium Pharmaceuticals, Inc.; March 2021. Available at https://www.ninlaro.com/prescribing-information.pdf. Accessed April 2, 2021.
2. National Comprehensive Cancer Network Drug and Biologics Compendium. Available at www.nccn.org. Accessed April 2, 2021.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 5.2021. Available at nccn.org. Accessed April 2, 2021.
4. National Comprehensive Cancer Network. Systemic Light Chain Amyloidosis Version 2.2021. Available at nccn.org. Accessed April 2, 2021.
5. National Comprehensive Cancer Network. Waldenstrom Macroglobulinemia / Lymphoplasmacytic Lymphoma Version 1.2021. Available at nccn.org. Accessed April 2, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	05.08.18	08.18
3Q 2019 annual review: NCCN recommended off-label use added for systemic light chain amyloidosis; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	05.14.19	08.19
3Q 2020 annual review: NCCN recommended uses for MM and Waldenstrom added; references reviewed and updated.	05.12.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	04.02.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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