Ninlaro® (ixazomib)
(Oral)

Document Number: IC-0261

Last Review Date: 10/28/2019
Date of Origin: 12/04/2015
Dates Reviewed: 12/04/2015, 10/2016, 10/2017, 10/2018, 11/2019

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 2.3 mg capsule: 3 capsules per 28 days
- 3 mg capsule: 3 capsules per 28 days
- 4 mg capsule: 3 capsules per 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 12 mg per 28 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

Multiple Myeloma†

- Used as initial therapy; **AND**
  - Used in combination with lenalidomide and dexamethasone in patients who are not transplant candidates; **OR**
  - Used in combination with cyclophosphamide and dexamethasone in patients who are transpant candidates; **OR**
- Used as maintenance therapy ; **AND**
  - Used as single agent therapy in patients who are transplant candidates; **AND**
    - Patient is symptomatic after response to primary myeloma therapy; **OR**
    - Patient has a response or stable disease following autologous stem cell transplant
- Used for relapsed or progressive disease; **AND**

Proprietary & Confidential
© 2019 Magellan Health, Inc.

- Dexamethasone with or without lenalidomide or cyclophosphamide after failure of at least one prior therapy; **OR**
- Dexamethasone and pomalidomide after disease progression following at least two prior therapies, including an immunomodulatory agent [i.e. lenalidomide or thalidomide] and proteasome inhibitor [i.e. bortezomib, carfilzomib, etc], within 60 days of completion of the last therapy

Systemic Light Chain Amyloidosis†

- Used for relapsed or refractory disease; **AND**
- Used in combination with or without dexamethasone

†FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe diarrhea, constipation, thrombocytopenia, neutropenia, peripheral neuropathy, peripheral edema, hepatotoxicity, severe rash, etc.

V. Dosage/Administration

Indication	Dose
Multiple myeloma	4 mg orally once a week on Days 1, 8, and 15 of a 28-day cycle. Given in combination with lenalidomide and dexamethasone. Treatment should be continued until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS code:

- C9399 - Unclassified drugs or biologicals
- J8999 - Prescription drug, oral, chemotherapeutic, nos

NDC:

- 2.3 mg capsule: 63020-0078-xx
- 3 mg capsule: 63020-0079-xx
- 4 mg capsule: 63020-0080-xx

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2019, Magellan Rx Management

VII. References

1. Ninlaro [package insert]. Cambridge, MA; Takeda Pharmaceutical Co. Ltd; November 2016. Accessed October 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ixazomib. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
E85.81	Light chain (AL) amyloidosis
E85.89	Other amyloidosis
E85.9	Amyloidosis unspecified
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2019, Magellan Rx Management

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2019, Magellan Rx Management