UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2021 P 1173-7 |
| Program | Prior Authorization/Notification |
| Medication | Ninlaro® (ixazomib) |
| P&T Approval Date | 1/2016, 4/2016, 3/2017, 3/2018, 3/2019, 3/2020, 3/2021 |
| Effective Date | 6/1/2021;<br>Oxford only: 6/1/2021 |

## 1. Background:

Ninlaro® (ixazomib) is a proteasome inhibitor indicated in combination with Revlimid® (lenalidomide) and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.[1]

The National Comprehensive Cancer Network (NCCN) also recommends use of Ninlaro as primary therapy for multiple myeloma, in combination with Revlimid and dexamethasone, as combination therapy in patients who have received at least one prior therapy for relapse or for progressive disease, or as maintenance, single agent therapy for transplant candidates with symptomatic multiple myeloma after response to primary therapy or response or stable disease following autologous stem cell transplant. NCCN also recommends the use of Ninlaro for treatment of relapsed or refractory systemic light chain amyloidosis in combination with or without dexamethasone. NCCN also recommends the use of Ninlaro for treatment of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma in combination with rituximab and dexamethasone.[2]

**Coverage Information:**
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

## 2. Coverage Criteria:

**A. <u>Patients less than 19 years of age</u>**

1. **Ninlaro** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

**Authorization will be issued for 12 months.**

**B. Multiple Myeloma**

1. **Initial Authorization**

a. **Ninlaro** will be approved based on **both** of the following criteria:

(1) Diagnosis of multiple myeloma

**-AND-**

(2) **One** of the following:

(a) **Both** of the following:

i. Patient has received at least one prior therapy for multiple myeloma [e.g., Velcade (bortezomib)]

**-AND-**

ii. Used as part of combination regimen including dexamethasone [combination regimen may include additional agents, such as Revlimid (lenalidomide)]

**-OR-**

(b) **Both** of the following:

i. Used as primary therapy

**-AND-**

ii. Used in combination with dexamethasone and Revlimid (lenalidomide)

**-OR-**

(c) **Both** of the following:

i. Patient is a transplant candidate

**-AND-**

ii. **One** of the following:
a. Patient has symptomatic disease following response to primary

myeloma therapy
b. Response or stable disease following autologous stem cell transplant

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Ninlaro** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Ninlaro therapy

**Authorization will be issued for 12 months.**

**C. Systemic Light Chain Amyloidosis**

1. **Initial authorization**

a. **Ninlaro** will be approved based on the following criterion:

(1) Diagnosis of relapsed or refractory systemic light chain amyloidosis

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Ninlaro** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Ninlaro therapy

**Authorization will be issued for 12 months.**

**D. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma**

1. **Initial authorization**

a. **Ninlaro** will be approved based on **both** of the following criteria:

(1) Diagnosis of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma

**-AND-**

(2) Used in combination with Rituxan (rituximab) and dexamethasone

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Ninlaro** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Ninlaro therapy

**Authorization will be issued for 12 months.**

**E. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

**Authorization will be issued for 12 months.**

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**


1. Ninlaro [package insert]. Cambridge, MA: Takeda Pharmaceutical Company Ltd.; February 2020
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed January 28, 2021.

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| **Change Control** | |
| 1/2016 | New program. |
| 4/2016 | Removed Revlimid & dexamethasone requirement from coverage criteria per NCCN. Updated background and references. |
| 3/2017 | Annual Review. Updated background information and criteria to include NCCN recommendation for primary use in combination with Revlimid and dexamethasone. |
| 3/2018 | Annual review with no changes to coverage criteria. Updated reference. |
| 3/2019 | Annual review. Updated background information and criteria to include NCCN recommendation for relapsed/refractory systemic light chain amyloidosis. Updated criteria for multiple myeloma as Ninlaro is no longer recommended alone for relapsed or progressive disease. Updated reference. |
| 3/2020 | Annual review. Updated background information and criteria to include NCCN recommendation for transplant candidates, and Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma. Added standard language for NCCN recommended regimens. Updated reference. |
| 3/2021 | Annual review. Updated references. |