UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1173-12
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, 3/2022, 3/2023, 3/2024, 6/2024, 6/2025
Effective Date	9/1/2025

1. Background:

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

Limitations of Use:
Ninlaro is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials.

The National Comprehensive Cancer Network (NCCN) also recommends use of Ninlaro as primary or maintenance therapy for multiple myeloma, for treatment of relapsed or refractory systemic light chain amyloidosis, and for treatment of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma in combination with rituximab and dexamethasone.

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]:

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. <u>Multiple Myeloma</u>

1. **<u>Initial Authorization</u>**

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

(1) Diagnosis of multiple myeloma

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:

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(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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.; July 2024
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed May 2, 2025.

Program	Prior Authorization/Notification – Ninlaro (ixazomib)
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

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	Macroglobulinemia/Lymphoplasmacytic Lymphoma. Added standard language for NCCN recommended regimens. Updated reference.
3/2021	Annual review. Updated references.
3/2022	Annual review. Updated references.
3/2023	Annual review with no change to coverage criteria. Updated background and references. Added state mandate footnote.
3/2024	Annual review. Updated background and coverage criteria per NCCN guidelines. Updated references.
6/2024	Updated Multiple Myeloma criteria to only diagnosis.
6/2025	Annual review with no change to coverage criteria. Updated background and reference.

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