UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Ninlaro

Program	Prior Authorization
Medication	Ninlaro® (ixazomib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	8/2016
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

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 stable disease following autologous stem cell transplant.[2] 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]

2. Coverage Criteria:

A. <u>Multiple Myeloma</u>

1. <u>Initial Authorization</u>

a. **Ninlaro** will be approved based on **<u>both</u>** of the following criteria:

(1) Diagnosis of multiple myeloma

-AND-

(2) **<u>One</u>** 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 a combination regimen including dexamethasone [Note: combination regimen may include additional agents, such as Revlimid]

-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

-OR-

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.

B. 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.

C. 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 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.

D. NCCN Recommended Regimens

1. Initial Authorization

a. **Ninlaro** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Ninlaro therapy

Authorization will be issued for 12 months.

3. References:

1. Ninlaro [package insert]. Takeda Pharmaceutical Company Ltd.: Cambridge, MA; November 2016.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed February 3, 2020.

Program	Prior Authorization –Ninlaro (ixazomib)
Change Control	
Date	Change
8/1/2016	New program
3/2017	Annual Review. Updated background information and criteria to include NCCN recommendation for primary use in combination with Revlimid and dexamethasone. Updated references and policy template.
3/2018	Added NCCN recommended regimen review criteria. Updated references.
3/2019	Updated background and criteria to include NCCN recommendations for relapsed/refractory systemic light chain amyloidosis. Updated criteria for multiple myeloma.

3/2020	Updated background information and criteria to include NCCN recommendation for transplant candidates, and Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma. Updated references.