UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Ninlaro

Program	Prior Authorization
Medication	Ninlaro® (ixazomib)
Issue Date	8/2016
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

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 monotherapy as primary therapy for multiple myeloma, in combination with Revlimid and dexamethasone or as or combination therapy in patients who have received at least one prior therapy for relapse or for progressive or refractory disease.[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) One of the following:

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

-OR-

(b) Both of the following:

i. Used as primary therapy

-AND-

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

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. 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 January 12, 2018.

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.