Specialty Guideline Management

NINLARO (ixazomib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Ninlaro is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

B. Compendial Uses
Multiple myeloma
1. In combination with lenalidomide and dexamethasone for active (symptomatic) myeloma as primary therapy or disease relapse after 6 months following primary therapy with the same regimen
2. In combination with dexamethasone for previously treated relapsed, refractory, or progressive disease

All other indications are considered experimental/investigational and are not covered benefits.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for treatment of multiple myeloma when EITHER of the following criteria is met:
1. Ninlaro is prescribed in combination with lenalidomide and dexamethasone, OR
2. Ninlaro is prescribed in combination with dexamethasone for relapsed, refractory, or progressive disease

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Ninlaro [package insert]. Cambridge, MA: Takeda Pharmaceutical Company Limited; November 2015.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 26, 2016.
3. The NCCN Clinical Practice Guidelines in Oncology® Multiple Myeloma (Version 1.2017) © 2016 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 20, 2016.