

# Ninlaro (ixazomib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

  

Medications	Quantity Limit
Ninlaro (ixazomib)	May be subject to quantity limit

## **APPROVAL CRITERIA**

Requests for Ninlaro (ixazomib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Multiple myeloma; **AND**
  - II. Individual has received at least one prior therapy; **AND**
  - III. Ninlaro (ixazomib) is given in combination with dexamethasone with or without lenalidomide (Label, NCCN 2A); **OR**
  - IV. Ninlaro is given in combination with dexamethasone and cyclophosphamide (NCCN 2A);
- OR**
- V. Individual has a diagnosis of multiple myeloma; **AND**
  - VI. Individual has received at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor; **AND**
  - VII. Individual has demonstrated disease progression on or within 60 days of completion of last therapy; **AND**
  - VIII. Ninlaro (ixazomib) is given as part of a treatment regimen containing dexamethasone and pomalidomide (NCCN 2A);
- OR**
- IX. Individual has a diagnosis of multiple myeloma; **AND**
  - X. Individual is using as primary therapy; **AND**
  - XI. Ninlaro is given in combination with cyclophosphamide and dexamethasone; **AND**
  - XII. Other therapies are less appropriate due to concomitant clinical conditions of renal insufficiency or peripheral neuropathy (NCCN 2A);
- OR**
- XIII. Individual has a diagnosis of Waldenström macroglobulinemia/Lymphoplasmacytic lymphoma; **AND**
  - XIV. Individual is using in combination with rituximab and dexamethasone (NCCN 2A, DP BIIa);
- OR**
- XV. Individual has a diagnosis of systemic light chain amyloidosis; **AND**

- XVI. Individual has received at least 1 prior line of therapy and has relapsed/refractory disease; **AND**
- XVII. Individual is using Ninlaro in combination with dexamethasone with or without lenalidomide (NCCN 2A, BP BIIa).

**Key References:**

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 14, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. Santhorawala V, Palladini G, Kukreti V, et al. A phase ½ study of the oral proteasome inhibitor ixazomib in relapsed or refractory AL amyloidosis. Blood 2017; 130:597-605.
5. Castillo JJ, Meid K, Gustine JN, et al. Prospective clinical trial of ixazomib, dexamethasone, and rituximab and primary therapy in Waldenstrom macroglobulinemia. Clin Cancer Res 2018;24:3247-3252.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 14, 2023.
  - a. Multiple Myeloma V1.2024. September 22, 2023.
  - b. Systemic Light Chain Amyloidosis V2.2023. Revised November 28, 2022.
  - c. Waldenstrom Macroglobulinemia/Lymphoplasmacytic lymphoma V1.2024. Revised September 28, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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