

Specialty Guideline Management

Ninlaro

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ninlaro	ixazomib

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.

FDA-Approved Indication¹

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.

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.

Compendial Uses²

- Multiple Myeloma
- Systemic Light Chain Amyloidosis
- Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma

- POEMS (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal Protein, Skin Changes) Syndrome
- Plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD)
- Plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:
test results confirming presence of chromosomal translocation t(11;14) where applicable.

Coverage Criteria

Multiple Myeloma

Authorization of 12 months may be granted for treatment of multiple myeloma when any of the following criteria is met:

- The requested medication is prescribed in combination with lenalidomide and dexamethasone.
- The requested medication is prescribed in combination with pomalidomide and dexamethasone for member who have received at least two prior therapies including an immunomodulatory agent and a proteasome inhibitor if lenalidomide- or anti-CD-38 refractory.
- The requested medication is prescribed in combination with cyclophosphamide and dexamethasone for members who have received at least one prior therapy.
- The requested medication is prescribed in combination with venetoclax and dexamethasone for member with t(11;14) who have received at least one prior therapy.
- The requested medication is prescribed as a substitute for bortezomib or carfilzomib when used as primary treatment or treatment for relapsed disease if the member previously received the requested medication as primary induction therapy for non-transplant candidates.

Systemic Light Chain Amyloidosis

Authorization of 12 months may be granted for treatment of relapsed or refractory systemic light chain amyloidosis when any of the following criteria is met:

- The requested medication is prescribed in combination with dexamethasone.
- The requested medication is prescribed in combination with lenalidomide and dexamethasone.
- The requested medication is prescribed in combination with cyclophosphamide and dexamethasone.

Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma

Authorization of 12 months may be granted for treatment of Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma when the requested medication is prescribed in combination with rituximab and dexamethasone.

POEMS (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal Protein, Skin Changes) Syndrome, plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD), plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)^{2,3}

Authorization of 12 months may be granted for treatment of POEMS syndrome, plasma cell-related MIDD, or plasma cell-related MGRS when the requested medication is prescribed in combination with lenalidomide and dexamethasone.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Ninlaro [package insert]. Cambridge, MA: Takeda Pharmaceuticals America, Inc.; July 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed October 17, 2025.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma. Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed October 7, 2025.