PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Ninlaro Prior Authorization Policy
- Ninlaro® (ixazomib capsules – Takeda)

REVIEW DATE: 04/24/2024

OVERVIEW

Ninlaro, an oral proteasome inhibitor, is indicated in combination with lenalidomide and dexamethasone for treatment of patients with **multiple myeloma** who have received at least one prior therapy.[1]

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.

Ninlaro should be taken once a week on the same day and at approximately the same time for the first 3 weeks of a 4-week cycle. There are dose modification guidelines which are recommended to manage treatment-related adverse events, including platelet count, absolute neutrophil count (ANC), and other toxicities (e.g., rash, peripheral neuropathy). Treatment should be continued until disease progression or unacceptable toxicity. Safety and efficacy are not established in patients < 18 years of age.

Guidelines

Ninlaro is discussed in various guidelines from the National Comprehensive Cancer Network (NCCN).

- **Multiple Myeloma:** NCCN guidelines (version 3.2024 – March 8, 2024) list multiple therapeutic regimens that may be used for primary therapy and previously treated multiple myeloma.[2] For primary therapy, in transplant candidates, Ninlaro/cyclophosphamide/dexamethasone (category 2A) and Ninlaro/lenalidomide/dexamethasone (category 2B) are listed under "Useful in certain circumstances". Ninlaro/lenalidomide/dexamethasone is a category 2A recommendation for non-transplant candidates under "Other recommended regimens". Ninlaro may be substituted for Kyprolis (carfilzomib intravenous infusion). Maintenance with Ninlaro is also listed among the alternatives for transplant and non-transplant candidates (category 2B for both settings). For previously treated disease, multiple regimens are listed, including Ninlaro/lenalidomide/dexamethasone (preferred, category 1), Ninlaro/Pomalyst (pomalidomide capsules)/dexamethasone (preferred for "Bortezomib-refractory" group), and Ninlaro/cyclophosphamide/dexamethasone under "Other recommended regimens for early relapses (1-3 prior therapies).
- **Systemic Light Chain Amyloidosis:** NCCN guidelines (version 2.2024 – December 12, 2023) list Ninlaro/cyclophosphamide/dexamethasone, Ninlaro ± dexamethasone and Ninlaro/lenalidomide/dexamethasone among the treatment options for patients with previously treated disease (both category 2A).[3]
- **Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma:** NCCN guidelines (version 2.2024 – December 5, 2023) list Ninlaro/rituximab/dexamethasone (category 2A) among the treatment options for primary therapy and for previously treated disease.[4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ninlaro. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ninlaro is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Multiple Myeloma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Ninlaro will be taken in combination with lenalidomide or cyclophosphamide and dexamethasone; OR
     - **ii.** Patient has received at least ONE prior regimen for multiple myeloma; OR
       Note: Examples include regimens containing bortezomib, cyclophosphamide, Kyprolis (carfilzomib intravenous infusion), lenalidomide, Darzalex (daratumumab intravenous infusion).
     - **iii.** The medication will be used following autologous stem cell transplantation (ASCT).

Other Uses with Supportive Evidence

2. **Systemic Light Chain Amyloidosis.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried at least one other regimen for this condition.
     Note: Examples of agents used in other regimens include bortezomib, lenalidomide, cyclophosphamide, and melphalan.

3. **Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is used in combination with a rituximab product and dexamethasone.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ninlaro is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Ninlaro® capsules [prescribing information]. Cambridge, MA: Takeda; March 2024.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 15, 2024.
3. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (version 2.2024 – December 12, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 15, 2024.
4. The NCCN Waldenstrom Macroglobulinemia/Lymphoblastic Lymphoma Clinical Practice Guidelines in Oncology (version 2.2024 – December 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 15, 2024.