



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **Background**

Ninlaro is the first oral proteasome inhibitor approved to treat multiple myeloma in patients who have received at least one prior therapy. Ninlaro is to be used in combination with dexamethasone, an anti-inflammatory medication. Multiple myeloma causes plasma cells to rapidly multiply and crowd out other healthy blood cells from the bone marrow. When the bone marrow has too many plasma cells, the cells may move to other parts of the body. Ninlaro works by blocking enzymes, known as 20S proteasomes, from multiple myeloma cells and hinder their ability to grow and survive. Ninlaro should be taken once a week on the same day and approximately the same time for the first 3 weeks of the 4 week cycle. Treatment should be continued until disease progression or unacceptable toxicity (1).

### **Regulatory Status**

FDA-approved indication: Ninlaro is a proteasome inhibitor indicated in combination with lenalidomide and dexamethasone for the 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 (1).

### Off-Label Use: (2-3)

1. Relapsed or refractory multiple myeloma (MM) - used in combination with dexamethasone.

Patients should be monitored for thrombocytopenia, gastrointestinal toxicities, peripheral neuropathy, peripheral edema, cutaneous reactions, hepatotoxicity, and embryo-fetal toxicity. Platelet counts and absolute neutrophil counts should be monitored at baseline, at least monthly during treatment, and more frequently during the first three cycles of Ninlaro. The most common laboratory abnormalities were low platelets (thrombocytopenia) and low absolute neutrophil count (neutropenia). Women should avoid getting pregnant while on this medication (1).

The safety and effectiveness of Ninlaro in pediatric patients less than 18 years of age have not been established (1).



**BlueCross  
BlueShield**

Federal Employee Program.

**NINLARO**  
(ixazomib)

## **Summary**

Ninlaro is the first oral proteasome inhibitor approved to treat multiple myeloma in patients who have received at least one prior therapy. Ninlaro is to be used in combination with dexamethasone, an anti-inflammatory medication. Female patients should avoid getting pregnant while on this medication. The safety and effectiveness of Ninlaro in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Ninlaro while maintaining optimal therapeutic outcomes.

## **References**

1. Ninlaro [package insert]. Cambridge, MA: Takeda Pharmaceutical Company Limited; July 2024.
2. NCCN Drugs & Biologics Compendium® Ixazomib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 13, 2025.
3. NCCN Clinical Practice Guidelines in Oncology® Multiple Myeloma (Version 1.2025). National Comprehensive Cancer Network, Inc. September 2024. Accessed on January 13, 2025.