IXAZOMIB

Generic	Brand	HICL	GCN	Exception/Other
IXAZOMIB CITRATE	NINLARO	42826		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma and have **ALL** of the following criteria been met?
   - Ninlaro (ixazomib) will be used in combination with lenalidomide and dexamethasone
   - Patient has received at least one prior therapy for the treatment of multiple myeloma such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

   If yes, **approve for 12 months by HICL with a quantity limit of #3 capsules per 28 days.**
   If no, do not approve.
   DENIAL TEXT: Our guideline for **IXAZOMIB (Ninlaro)** requires a diagnosis of multiple myeloma and that it will be used in combination with lenalidomide and dexamethasone in patients who have received at least one prior therapy such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation.

RATIONALE

Promote appropriate utilization of IXAZOMIB (Ninlaro) based on FDA approved indication.

Ninlaro, in combination with lenalidomide and dexamethasone offers the first all-oral treatment option for patients with relapsed and/or refractory multiple myeloma (RRMM). According to the National Cancer Institute (NCI), MM is the third most common blood cancer (after lymphoma and leukemia) in the United States. NCI estimates there will be 26,850 new cases of multiple myeloma and 11,240 related deaths in the US this year.

Standard treatment options for MM include proteasome inhibitors (Velcade [bortezomib], Kyprolis [carfilzomib]), immunomodulators (IMiDs) (Revlimid [lenalidomide], Thalomid [thalidomide], Pomalyst [pomalidomide]), alkylating agents (Alkeran [melphalan], Cytoxan [cyclophosphamide]), anthracyclines (Doxil [liposomal doxorubicin]), and corticosteroids (dexamethasone). Regimens may contain two or three drug combinations, with selected patients undergoing hematopoietic cell transplantation (HCT).

NCCN guidelines added a category 1 recommendation for Ninlaro in combination with lenalidomide and dexamethasone for previously untreated MM. While ongoing studies are evaluating Ninlaro for newly diagnosed MM, current labeling for Ninlaro requires at least one prior line of therapy, as the FDA approval was based only on patients with RRMM. Although Ninlaro has the convenience of an all-oral regimen, it should be reserved for patients who have progressed on currently recommended regimens.

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RATIONALE (CONTINUED)
The efficacy of Ninlaro was evaluated in a phase 3, randomized, double-blind, placebo-controlled, multicenter trial (Tourmaline-MM1) in 722 patients with RRMM. Patients had to receive at least one prior line of therapy (60-62% received one, 38-40% received two or three), but patients who were refractory to lenalidomide or PIs (e.g., Velcade) were excluded from the study. The most common types of prior therapy included melphalan-containing (80-81%), bortezomib-containing (69%), thalidomide-containing (44-47%), and stem cell transplantation (55-59%). Other prior therapies included lenalidomide-containing and carfilzomib containing regimens.

FDA APPROVED INDICATION
Indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

DOSAGE
The recommended starting dose of Ninlaro (ixazomib) is 4mg taken orally on Days 1, 8, and 15 of a 28-day cycle. Treatment should be continued until disease progression or unacceptable toxicity.

The dose may be reduced due to adverse reactions as shown in the table below.

Recommended starting dose	First reduction to	Second reduction to	Discontinue
4mg	3mg	2.3mg	

REFERENCES

- Ninlaro [Prescribing Information]. Cambridge, MA: Takeda Pharmaceutical Company Limited; 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/16
Created: 12/15
Client Approval: 02/16
P&T Approval: 02/16