Clinical Policy: Ixazomib (Ninlaro)

Reference Number: PA.CP.PHAR.302
Effective Date: 01/18
Last Review Date: 11/17

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness ® clinical policy for ixazomib capsules for oral use (Ninlaro®).

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness ® that Ninlaro is **medically necessary** when the following criteria is met:

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of multiple myeloma;
2. Meets a or b:
   a. FDA approved use (i and ii):
      i. Prescribed in combination with lenalidomide and dexamethasone;
      ii. Member has received ≥ 1 prior therapy;
   b. Off-label NCCN recommended use:
      i. Prescribed in one of the following ways (a or b):
         a) As primary therapy in combination with lenalidomide and dexamethasone for active (symptomatic) disease;
         b) As subsequent therapy in combination with dexamethasone for disease relapse or for progressive or refractory disease.

Approval duration: 3 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Multiple Myeloma (must meet all)**:**

Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

1.
2. Member has none of the following reasons to discontinue:
   a. Disease progression or unacceptable toxicity;
   b. Grade 4* (life-threatening):
      i. Rash;
      ii. Peripheral neuropathy.

**Grading based on National Cancer Institute Common Terminology Criteria (CTCAE).*

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Ixazomib is a reversible proteasome inhibitor. Ixazomib preferentially binds and inhibits the chymotrypsin-like activity of the beta 5 subunit of the 20S proteasome. Ixazomib induced apoptosis of multiple myeloma cell lines in vitro. Ixazomib demonstrated *in vitro* cytotoxicity against myeloma cells from patients who had relapsed after multiple prior therapies, including bortezomib, lenalidomide, and dexamethasone. The combination of ixazomib and lenalidomide demonstrated synergistic cytotoxic effects in multiple myeloma cell lines. *In vivo*, ixazomib demonstrated antitumor activity in a mouse multiple myeloma tumor xenograft model.

Formulations:

Ninlaro is available as 4 mg, 3 mg, and 2.3 mg capsules for oral administration.

FDA Approved Indications:

Ninlaro (ixazomib) is a proteasome inhibitor/oral capsule formulation indicated:

- In combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date

References

1. Ninlaro prescribing information. Cambridge, MA: Millennium Pharmaceuticals, Inc.; November 2016. Available at https://www.ninlaro.com/prescribing-information.pdf . Accessed January 26, 2017.

2. Ixazomib. In: National Comprehensive Cancer network Drug and Biologics Compendium. Available at www.NCCN.org. Accessed January 26, 2017.
3. Multiple myeloma (Version 3.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 26, 2017.