Clinical Policy Title:	ixazomib
Policy Number:	RxA.418
Drug(s) Applied:	Ninlaro®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of multiple myeloma;
2. Used in combination with Revlimid and dexamethasone;
3. Member has received at least one (1) prior therapy for multiple myeloma (e.g. Revlimid, Thalomid, Velcade).

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Systemic Light Chain Amyloidosis (off-label) (must meet all):

1. Diagnosis of relapsed or refractory systemic light chain amyloidosis;
2. Prescribed as single agent or in combination with dexamethasone with or without lenalidomide.

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Waldenstrom Macroglobulinemia/ Lymphoplasmacytic Lymphoma (off-label) (must meet all):

1. Diagnosis of waldenstrom macroglobulinemia/ lymphoplasmacytic lymphoma.
2. Prescribed in combination with rituximab and dexamethasone.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Multiple Myeloma. version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Systemic Light Chain Amyloidosis version 2.2024. Available at:

https://www.nccn.org/professionals/physician_gls/pdf/amyloidosis.pdf. Accessed August 28, 2024.
3. National Comprehensive Cancer Network. Waldenstrom Macroglobulinemia/ Lymphoplasmacytic Lymphoma; Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Initial and Continued approval duration was updated to include Medicaid, Commercial & HIM approval duration. 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 5. References were reviewed and updated.	07/22/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.4 was updated to include "with multiple myeloma who have received at least one prior therapy…" 2. Initial Approval Criteria I.A.5 was updated to include "Primary therapy for symptomatic multiple myeloma or for disease…" 3. Initial Approval Criteria I.A.6 was updated to include "Therapy for previously treated multiple myeloma for relapse or progressive disease…" 4. Initial Approval Criteria I.B.4 was updated to include "Prescribed as single agent or in combination with dexamethasone…" 5. Initial Approval Criteria I.C was updated to include off-label indication, "Waldenstrom Macroglobulinemia/ Lymphoplasmacytic Lymphoma (off-label)…" 6. Initial Approval Criteria and Continued Therapy Approval Criteria have been updated to remove HIM approval duration. 7. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 8. References were reviewed and updated.	06/03/2021	9/14/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.4: Updated to remove prior combination therapy criteria "Prescribed in combination with dexamethasone and lenalidomide in patients with multiple myeloma who have received at	03/25/2022	07/18/2022

least one prior therapy". 2. Initial Approval Criteria, I.A.5: Updated to remove prior combination therapy criteria "Primary therapy for symptomatic multiple myeloma or for disease relapse after 6 months following primary induction therapy with the same regimen in combination with": a. Lenalidomide and dexamethasone (2B recommendation per NCCN); b. Cyclophosphamide and dexamethasone for transplant patients; 3. Initial Approval Criteria, I.B.4: Updated combination therapy criteria from Prescribed as single agent or in combination with dexamethasone; to Prescribed as single agent or in combination with dexamethasone with or without lenalidomide;. 4. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.4: Updated to include new combination therapy criteria Used in combination with Revlimid and dexamethasone. 2. Initial Approval Criteria, I.A.5: Updated prior combination therapy criteria from Member meets one (1) of the following (a or b): a. Therapy for previously treated multiple myeloma for relapse or progressive disease in combination with (i, ii ,iii or iv): i. Dexamethasone and lenalidomide (preferred regimen); ii. Dexamethasone and pomalidomide for patients who have received at least 2 prior therapies including an immunomodulatory agent and a proteasome inhibitor and who have demonstrated disease progression on or within 60 days of completion of the last therapy (preferred regimen); iii. Cyclophosphamide and dexamethasone; iv. Dexamethasone (used in certain circumstances); b. Used as maintenance therapy as a single agent for transplant candidates with (i or ii): i. Symptomatic multiple myeloma after response to primary myeloma therapy; ii. Response or stable disease following autologous hematopoietic cell transplant; *Prior authorization is required for Revlimid and Pomalyst to Members has received at least one (1) prior therapy	04/21/2023	07/13/2023

for multiple myeloma (e.g. Revlimid, Thalomid, Velcade). 3. Initial Approval Criteria, I.A, I.B & I.C: Updated Approval duration from 6 to 12 months for Commercial. 4. Continued Therapy Approval Criteria, II.A: Updated Approval duration from 6 to 12 months for Commercial. 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024