

Clinical Policy Title:	neratinib
Policy Number:	RxA.245
Drug(s) Applied:	Nerlynx®
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Breast Cancer (must meet all):

1. Diagnosis of HER2 positive breast cancer;
2. Prescribed in one of the following ways (a or b):
 - a. In combination with capecitabine for advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in metastatic setting;
 - b. Given as extended adjuvant treatment of early stage HER2-overexpressed/amplified breast cancer used following 1 year of adjuvant trastuzumab based therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Central Nervous System Cancers (off label use) (must meet all):

1. Diagnosis of limited or extensive brain metastases in patients with HER2 positive breast cancer;
2. Prescribed in combination with capecitabine.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications (member meets 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. Breast Cancer Version 4.2024- Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 27, 2024.
2. National Comprehensive Cancer Network. Central Nervous System Cancers Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed August 27, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Policy description table updated 2. Initial therapy criteria I.A.4a. was updated and I.A.4b was added per latest prescribing information 3. Continuation therapy criteria II.A.1. was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance” Appendix A was updated to include “HER2” 4. References were updated 	07/13/2020	09/14/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial and continued therapy approval criteria was created for Central Nervous System Cancers (off label use). 2. Approval duration for Initial Approval Criteria was updated to 12 months from 6 months. 3. References were updated. 	03/05/2020	06/10/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. References were reviewed and updated. 	01/20/2022	4/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria I.B.4: Updated from Prescribed in combination with capecitabine for recurrent, advanced, or metastatic disease, and member has received two or more prior anti-HER2 based regimens used in the metastatic setting to Prescribed in combination with capecitabine; 2. References were reviewed and updated. 	12/29/2022	04/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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. Reauthorization criteria for all the diagnosis merged under “All Indications in Section I”. 7. Updated approval duration verbiage. 	8/27/2024	9/13/2024

8. References were reviewed and updated.		
Policy was reviewed.	12/05/2024	N/A
Policy reviewed	12/11/2025	12/11/2025