Clinical Policy Title:	neratinib
Policy Number:	RxA.245
Drug(s) Applied:	Nerlynx®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
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 by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. 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;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 240 mg (6 tablets) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 12 months
Medicaid: 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 by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with capecitabine;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 240 mg (6 tablets) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Breast Cancer (member meets all):

1. Member is currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving Nerlynx® for breast cancer and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 240 mg (6 tablets) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 12 months
Medicaid: 12 months

B. Central Nervous System Cancers (off label use) (member meets all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 240 mg (6 tablets) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network. Breast Cancer Version 4.2022- Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 29, 2022.
2. National Comprehensive Cancer Network. Central Nervous System Cancers Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed December 29, 2022.

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

Policy was reviewed: 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
Policy was reviewed: 1. References were reviewed and updated.	01/20/2022	4/18/2022
Policy was reviewed: 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
Policy was reviewed.	10/19/2023	10/19/2023