

Nerlynx (neratinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Nerlynx (neratinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Nerlynx (neratinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of HER2-overexpressed/amplified breast cancer confirmed by one of the following:

A. Immunohistochemistry (IHC) is 3+;

OR

B. In situ hybridization (ISH) positive;

AND

- II. Individual is using in one of the following ways (Label, NCCN 2A);

A. Individual has a diagnosis of early stage HER2-positive breast cancer; **AND**

B. Individual has previously completed adjuvant trastuzumab-based therapy;

OR

C. Individual has a diagnosis of recurrent unresectable, advanced, or metastatic HER2 positive breast cancer; **AND**

D. Individual is using in combination with capecitabine; **AND**

E. Individual has received two or more prior anti-HER2 based regimens (Label, NCCN 2A);

OR

F. Individual has a diagnosis of metastatic HER2 positive breast cancer with asymptomatic, recurrent, or relapsed brain metastases, **AND**

G. Individual is using in combination with capecitabine.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.

5. Saura C, Oliveira M, Feng YN, et al. Neratinib + capecitabine versus lapatinib + capecitabine in patients with HER2+ metastatic breast cancer previously treated with ≥ 2 HER2-directed regimens: findings from the multinational, randomized, phase III NALA trial. J Clin Oncol 2019; 37 (no. 15_suppl): Abstract 1002.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed April 14, 2023.
 - a. Breast Cancer. V4.2023. Revised March 23, 2023.
 - b. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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