

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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 early stage 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 has previously completed adjuvant trastuzumab-based therapy;
- OR**
- III. Individual has a diagnosis of advanced or metastatic Breast Cancer, including asymptomatic or stable brain metastases from breast cancer, with HER 2 overexpression confirmed by one of the following
 - A. Immunohistochemistry (IHC) is 3+;
 - OR**
 - B. In situ hybridization (ISH) positive;
- AND**
- IV. Individual is using in combination with capecitabine; **AND**
- V. Individual has received two or more prior anti-HER2 based regimens in the metastatic setting (Label, Saura 2019).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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>. Accessed: April 19, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

CRX-ALL-0567-20

PAGE 1 of 2 06/10/2020
New Program Date 09/12/2017

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; 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™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed April 2020.
 - a. Breast Cancer. V3.2020. Revised March 6, 2020.
 - b. Central Nervous System Cancers. V1.2020. Revised March 10, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.