

Reference number(s)
2178-A

SPECIALTY GUIDELINE MANAGEMENT

NERLYNX (neratinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Nerlynx is indicated for the extended adjuvant treatment of adult patients with early stage human epidermal growth factor receptor (HER)2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab based therapy.

B. Compendial Uses

Metastatic central nervous system (CNS) lesions if active against primary tumor (breast)

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Breast cancer**

Authorization of up to 12 months total may be granted for the treatment of early stage HER2-positive breast cancer when Nerlynx is initiated after completing adjuvant trastuzumab based therapy.

B. **Metastatic CNS lesions**

Authorization of 12 months may be granted for the treatment of metastatic CNS lesions from HER2-positive breast cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Nerlynx [package insert]. Los Angeles, CA: Puma Biotechnology; June 2018.
2. Chan A, Delaloge S, Holmes FA, et al. Neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive breast cancer (ExteNET): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2016; 17(3):367-77.
3. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed January 16, 2019.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Central Nervous system cancers. Version 2. 2018. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 16, 2019.

Reference number(s)
2178-A

Nerlynx_PA_ALL_Rx

© 2019 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.