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.

FDA-Approved Indication

1. Nerlynx is indicated for the extended adjuvant treatment of adult patients with early stage human epidermal growth factor receptor (HER)2-positive breast cancer, to follow adjuvant trastuzumab based therapy.
2. Nerlynx is indicated in combination with capecitabine, for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting.

Compendial Uses

1. Recurrent HER2-positive breast cancer in combination with capecitabine
2. Brain metastases from HER2-positive breast cancer in combination with capecitabine

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of human epidermal growth factor receptor 2 (HER2) status is necessary to initiate the prior authorization review.

III. CRITERIA FOR INITIAL APPROVAL

Breast cancer

A. Authorization of up to 12 months total may be granted for treatment of early stage HER2-positive breast cancer when Nerlynx will be initiated after completing adjuvant trastuzumab-based therapy.
B. Authorization of 12 months may be granted for treatment of recurrent, advanced or metastatic (including brain metastases) HER2-positive breast cancer in combination with capecitabine.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication outlined in section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. Adjuvant treatment of early stage breast cancer will be approved for a total of 12 months of therapy.

V. REFERENCES

1. Nerlynx [package insert]. Los Angeles, CA: Puma Biotechnology; July 2020.
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® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 2, 2020.