Reference number(s)
2178-A

Specialty Guideline Management
Nerlynx

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nerlynx	neratinib

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 Indications[1]

- Nerlynx is indicated as a single agent for the extended adjuvant treatment of adult patients with early-stage human epidermal growth factor receptor 2 (HER2)-positive breast cancer, to follow adjuvant trastuzumab-based therapy.
- 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[3]

- HER2-positive breast cancer in combination with capecitabine
- Brain metastases from HER2-positive breast cancer in combination with capecitabine
- Breast cancer with HER2 activating mutations
- HER2-mutant cervical cancer

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

Documentation

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

Coverage Criteria

Breast cancer[1-3]

- Authorization of up to 12 months total may be granted for treatment of early stage HER2-positive breast cancer when the requested medication will be initiated after completing adjuvant trastuzumab-based therapy when used as a single agent.
- Authorization of 12 months may be granted for treatment of breast cancer with no response to preoperative systemic therapy or recurrent or metastatic (including brain metastases) HER2-positive breast cancer in combination with capecitabine.
- Authorization of 12 months may be granted for treatment of metastatic breast cancer with HER2 activating mutations when used in combination with fulvestrant and trastuzumab for third-line or later therapy when either of the following criteria are met:
  - The disease is hormone receptor positive and HER2-negative and the member previously received a cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitor [e.g., Ibrance (palbociclib), Kisqali (ribociclib), Verzenio (abemaciclib)]
  - The disease is triple negative

Cervical Cancer[3]

Authorization of 12 months may be granted for subsequent treatment of recurrent or metastatic HER2-mutant cervical cancer when used as a single agent.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section 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.

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References

1. Nerlynx [package insert]. Los Angeles, CA: Puma Biotechnology, Inc.; March 2022.
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® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed February 12, 2025.