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-overexpressed/amplified 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.

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 advanced or metastatic HER2-positive breast cancer in combination with capecitabine when the member has received two or more prior anti-HER2 based regimens in the metastatic setting.

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
