

Clinical Pharmacy Program Guidelines for Nerlynx

Program	Prior Authorization
Medication	Nerlynx [®] (neratinib)
Issue Date	9/2017
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

1. Background:

Nerlynx[®] (neratinib) is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy. The recommended duration of adjuvant Nerlynx treatment is one year.

2. Coverage Criteria:

A. Breast Cancer

1. Nerlynx will be approved based on **all** of the following criteria:

- a. Diagnosis of early stage breast cancer

-AND-

- b. Disease is human epidermal growth factor receptor 2 (HER2)-positive

-AND-

- c. Patient has received adjuvant trastuzumab (Herceptin[®]) treatment

Authorization will be issued for 12 months. Duration of coverage is limited to 12 months.

3. References:

1. Nerlynx[package insert]. Los Angeles, CA: Puma Biotechnology, Inc; July 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium[™]). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 7, 2017.

Program	Prior Authorization –Nerlynx (neratinib)
Change Control	
Date	Change
9/2017	New program