UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Nerlynx

Program	Prior Authorization
Medication	Nerlynx® (neratinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island
Issue Date	9/2017
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Nerlynx® (neratinib) is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy. The recommended duration of adjuvant Nerlynx treatment is one year. It is also indicated for use 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. The National Comprehensive Cancer Network (NCCN) also recommends the use of Nerlynx in combination with capecitabine or paclitaxel for the treatment of patients with HER-2 positive breast cancer with recurrent brain metastases.

2. Coverage Criteria:

A. <u>Early-Stage Breast Cancer</u>

1. Nerlynx will be approved based on **<u>all</u>** 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-based therapy (e.g., Herceptin, Kanjinti)

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

B. Breast Cancer with Brain Metastases

1. Initial Authorization

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

(1) Diagnosis of breast cancer

-AND-

(2) Patient has brain metastases

-AND-

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

-AND-

(4) Used in combination with **one** of the following:

(a) Xeloda (capecitabine)
(b) Paclitaxel

Authorization will be issued for 12 months.

2. Reauthorization

a. **Nerlynx** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Nerlynx therapy

Authorization will be issued for 12 months.

C. Advanced or Metastatic Breast Cancer

1. **Initial Authorization**

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

(1) Diagnosis of advanced or metastatic breast cancer

-AND-

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

-AND-

(3) Patient has received two or more prior anti-HER2 based regimens in metastatic setting

-AND-

(4) Will be used in combination with Xeloda (capecitabine)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Nerlynx** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Nerlynx therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

1. Initial Authorization

a. **Nerlynx** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Nerlynx** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Nerlynx therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Nerlynx [package insert]. Los Angeles, CA: Puma Biotechnology, Inc.; February 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 18, 2020.

Program	Prior Authorization –Nerlynx (neratinib)
Change Control	
Date	Change
9/2017	New program
9/2018	Updated background and criteria to include NCCN recommended use in patients with HER-2 positive breast cancer with recurrent brain metastases. Added standard NCCN Recommended Regimen criteria. Updated references.
9/2019	Annual review. Updated references.
4/2020	Updated background and criteria to reflect new indication for use in patients with advanced or metastatic disease in combination with capecitabine. Updated references.