VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Nerlynx Prior Authorization Policy
- Nerlynx® (neratinib tablets – Puma)

REVIEW DATE: 09/29/2021; selected revision 1/12/2022

OVERVIEW

Nerlynx, a kinase inhibitor, is indicated in adults for the following uses:[1]

- Early-stage human epidermal growth factor receptor 2 (HER2)-positive **breast cancer**, as a single agent for extended adjuvant therapy to follow adjuvant trastuzumab-based therapy.
- Advanced or metastatic HER2-positive **breast cancer**, in combination with capecitabine, for patients who have received two or more prior anti-HER2-based regimens in the metastatic setting.

Guidelines

Nerlynx is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Breast cancer:** NCCN guidelines (version 2.2022– December 20, 2021) note that Nerlynx can be considered as extended adjuvant therapy following adjuvant trastuzumab-containing therapy in patients with hormone receptor (HR)-positive, HER2-positive disease with a perceived high risk of recurrence.(category 2A).[2] The benefits or toxicities associated with extended Nerlynx in patients who have received Perjeta® (pertuzumab intravenous infusion) or Kadcyla® (ado-trastuzumab emtansine intravenous infusion) are unknown. The guidelines do not include recommendations for using Nerlynx extended adjuvant therapy in patients with HR-negative, HER2-positive disease. For the treatment of recurrent unresectable (local or regional) or Stage IV or metastatic disease, Nerlynx + capecitabine is listed as a category 2A recommended option in the third line and beyond setting.
- **Central nervous system cancers**: NCCN guidelines (version 2.2021 – September 8, 2021) list Nerlynx with capecitabine as a category 2A recommended therapy for breast cancer with HER2 positive disease for brain metastases; Nerlynx in combination with paclitaxel is also listed as a category 2B recommendation in this setting.[3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Nerlynx. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Nerlynx is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Breast Cancer – Adjuvant Therapy.** Approve for 1 year (total) if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient will not be using this medication in combination with HER2 antagonists.

Note: Examples of HER2 antagonists are trastuzumab or Perjeta (pertuzumab intravenous infusion).

C) Patient has human epidermal growth factor receptor 2 (HER2)-positive breast cancer; AND

D) Patient meets ONE of the following criteria (i or ii):

i. The medication is requested for extended adjuvant therapy after the patient has completed 1 year of adjuvant therapy with a trastuzumab intravenous product; OR

ii. Patient has tried adjuvant therapy with a trastuzumab intravenous product and could not tolerate 1 year of therapy, according to the prescriber.

2. Breast Cancer – Recurrent or Metastatic Disease. Approve for 3 years if the patient meets the following criteria (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND

B) Patient has human epidermal growth factor receptor 2 (HER2)-positive breast cancer; AND

C) The medication is used in combination with capecitabine; AND

D) Patient has tried at least two prior anti-HER2 based regimens.
Note: Examples include Perjeta (pertuzumab intravenous infusion) + trastuzumab + docetaxel, Perjeta + trastuzumab + paclitaxel; Kadcyla (ado-trastuzumab emtansine intravenous infusion), trastuzumab + capecitabine, Tykerb (lapatinib tablets) + capecitabine, trastuzumab + Tykerb.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Nerlynx is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Nerlynx® tablets [prescribing information]. Los Angeles, CA: Puma; June 2021.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2022– December 20, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 6, 2022.
3. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 2.2021 – September 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 27, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/23/2020
Annual Revision	**Breast Cancer – Adjuvant Therapy:** A requirement was added that the patient is ≥ 18 years of age. The requirement that the patient will not be using Nerlynx in combination with HER2 antagonists was added. A note was added with examples of HER2 antagonists. The following condition not recommended for approval was removed, "Concurrent Use of Nerlynx with Other Medications for Adjuvant or Neoadjuvant Treatment of HER2-Positive Breast Cancer". **Breast Cancer – Advanced or Metastatic Disease:** A requirement was added that the patient is ≥ 18 years of age.	09/29/2021
Selected Revision	**Breast Cancer – Recurrent or Metastatic Disease:** The condition of approval was reworded from "advanced" to "recurrent". Previously, the condition of approval was worded as "Breast Cancer – Advanced or Metastatic Disease". The requirement of "in the metastatic setting" was removed from the criteria that requires the patient to try at least two prior anti-HER2 based regimens.	01/12/2022