



## PRIOR AUTHORIZATION POLICY

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

**REVIEW DATE:** 10/18/2023

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### **INSTRUCTIONS FOR USE**

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## **CIGNA NATIONAL FORMULARY COVERAGE:**

### **OVERVIEW**

Nerlynx, a kinase inhibitor, is indicated in adults for the following uses:<sup>1</sup>

- 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:** Guidelines (version 4.2023 – March 23, 2023) 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).<sup>2</sup> The benefits or toxicities associated with extended Nerlynx in patients who have received Perjeta® (pertuzumab intravenous infusion) or Kadcyła® (ado-trastuzumab emtansine intravenous infusion) are unknown. For the treatment of recurrent unresectable (local or regional) or Stage IV or

metastatic HER2 positive disease, Nerlynx + capecitabine is recommended for fourth-line and beyond setting (category 2A).

- **Central nervous system cancers:** Guidelines (version 1.2023 – March 24, 2023) list Nerlynx + capecitabine (category 2A) and Nerlynx + paclitaxel (category 2B) for brain metastases for patients with HER2 positive breast cancer.<sup>3</sup>

## **POLICY STATEMENT**

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

- **Nerlynx® (neratinib tablets - Puma)**  
**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### **FDA-Approved Indications**

- 1. Breast Cancer – Adjuvant Therapy.** Approve for 1 year (total) if the patient meets the following (A, B, C, and D):
  - A)** Patient is  $\geq 18$  years of age; AND
  - B)** Patient will not be using this medication in combination with human epidermal growth factor 2 (HER2) antagonists.  
Note: Examples of HER2 antagonists are trastuzumab and Perjeta (pertuzumab intravenous infusion).
  - C)** Patient has HER2-positive breast cancer; AND
  - D)** Patient meets ONE of the following (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 1 year if the patient meets the following (A, B, C, and D):
  - A)** Patient is  $\geq 18$  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; Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion), Kadcylla (ado-trastuzumab emtansine intravenous infusion), Tukysa (tucatinib tablets) + trastuzumab + capecitabine, trastuzumab + capecitabine, lapatinib + capecitabine, trastuzumab + lapatinib.

## CONDITIONS NOT COVERED

- **Nerlynx® (neratinib tablets - Puma)** is(are) considered experimental, investigational, or unproven for ANY other use(s).

## REFERENCES

1. Nerlynx® tablets [prescribing information]. Los Angeles, CA: Puma; March 2022.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – March 23, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on October 17, 2023.
3. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2023 – March 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on October 17, 2023.

## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/19/2022
Annual Revision	No criteria changes.	10/18/2023

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