PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/26/2024

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 3.2024 – June 17, 2024) 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 and node positive (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. 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**: NCCN guidelines (version 1.2024 – May 31, 2024) list Nerlynx + capecitabine (category 2A) and Nerlynx + paclitaxel (category 2B) for brain metastases for patients with HER2 positive breast cancer.[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 ALL of the following (A, B, C, and D):
   A) Patient is ≥ 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 ALL of the following (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; Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion), Kadcyla (ado-trastuzumab emtansine intravenous infusion), Tukysa (tucatinib tablets) + trastuzumab + capecitabine, trastuzumab + capecitabine, lapatinib + capecitabine, trastuzumab + lapatinib.

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; March 2022.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – June 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2024.
3. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2024 – May 31, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2024