MEDICAL MUTUAL®

Drug Policy

Policy:	Nerlynx (neratinib)	Annual Review Date: 08/15/2024 Last Revised Date: 08/15/2024

OVERVIEW

Nerlynx is a tyrosine kinase inhibitor dosed once daily as a single agent adjuvant treatment for adults who have early stage HER2-overerxpressed/amplified breast cancer and in combination with capecitabine for 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. It is intended to be a preventive medication taken for one year to prevent breast cancer recurrence.

POLICY STATEMENT

This policy involves the use of Nerlynx. Prior authorization is recommended for pharmacy benefit coverage of Nerlynx. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Nerlynx as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Nerlynx be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Breast Cancer, Early Stage**
   Criteria. *Patient must meet the following criteria*
   - **a.** Nerlynx is used as an adjuvant treatment following adjuvant trastuzumab based therapy; AND
   - **b.** Antidiarrheal prophylaxis was initiated with the first dose of Nerlynx and provider will adjust the dose as necessary to manage the adverse effect; AND
   - **c.** Patient is 18 years of age or older; AND
   - **d.** The patient has HER2-positive breast cancer

2. **Breast Cancer, Recurrent or Metastatic Disease**
   Criteria. *Patient must meet the following criteria*

a. The patient has HER2-positive disease; AND
b. The patient has progressed on 2 or more prior regimens; AND
   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.
c. Nerlynx will be used in combination with capecitabine; AND
d. Antidiarrheal prophylaxis will be initiated with the first dose of Nerlynx and provider will adjust the dose as necessary to manage the adverse effect

3. Limited or Extensive Brain Metastases
Criteria. *Patient must meet the following criteria*

a. The patient has recurrent brain metastases and stable systemic disease; AND
b. Nerlynx will be used in combination with capecitabine or paclitaxel; AND
c. The patient has HER-2 positive breast cancer

4. Another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation
Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

5. Patient has been started on Nerlynx (continuation of therapy)
Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* For HER2-overexpressed/amplified Breast Cancer, continuation of therapy may be granted to complete 1 full year of treatment. If one full year has been given, approval cannot be granted. For other approvable indications, extended approval is 1 year.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Nerlynx tablets [prescribing information]. Los Angeles, CA: Puma Biotechnology, Inc.; February 2020.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 1.2018) 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 10, 2018.

3. Neratinib. In: DRUGDEX [online database}. Truven Health Analytics; Greenwood Village CO. Last updated 6 August 2020. Accessed on 11 August 2020.
4. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 11 August 2020.