



**NERLYNX
(neratinib)**

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Nerlynx (neratinib) is a tyrosine kinase inhibitor that irreversibly binds to epidermal growth factors, human epidermal growth factor 2 (HER2) and HER4. Nerlynx (neratinib) is clinically approved to be used in patients with HER2 protein positive breast cancer. Nerlynx effects have been shown to reduce risk of breast cancer recurrence (1).

Regulatory Status

FDA-approved indications: Nerlynx is a kinase inhibitor indicated: (1)

- As a single agent, for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy
- 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

Safety and effectiveness in pediatric patients have not been established (1).

Summary

Nerlynx (neratinib) is a tyrosine kinase inhibitor that irreversibly binds to epidermal growth factors, human epidermal growth factor 2 (HER2) and HER4. Nerlynx (neratinib) is clinically approved to be used in patients with HER2 protein positive breast cancer. The safety and effectiveness in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Nerlynx while maintaining optimal therapeutic outcomes.

References

1. Nerlynx [package insert]. Los Angeles, CA: Puma Biotechnology, Inc.; March 2022.
2. NCCN Drugs & Biologics Compendium® Neratinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2025.