Clinical Policy: Neratinib (Nerlynx)

Reference Number: CP. PHAR.365
Effective Date: 09.05.17
Last Review Date: 11.17 Revision Log
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Neratinib (Nerlynx®) is a kinase inhibitor that irreversibly binds to Epidermal Growth Factor Receptor (EGFR), Human Epidermal Growth Factor Receptor 2 (HER2), and HER4.

FDA Approved Indication
Nerlynx is indicated for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab based therapy.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Nerlynx is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (member meets all)**:**

1. Diagnosis of early stage (i.e., stage 1-3) HER2-positive breast cancer;
2. Age ≥ 18 years;
3. Documentation of previous treatment with Herceptin (trastuzumab) as adjuvant therapy;
4. Dose does not exceed 240 mg/day (6 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Breast Cancer (member meets all)**:**

1. Currently receiving medication via Centene benefit, or has previously met the initial approval criteria;
2. Member shows no evidence of relapse or significant toxicity;
3. Member has not received more than 12 months of therapy;
4. If request is for a dose increase, new dose does not exceed 240 mg/day (6 tablets/day).

Approval duration: Up to 12 months of total therapy*
**Total duration of therapy does not exceed 12 months*

B. Other diagnoses/indications (member meets 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
HER4: human epidermal growth factor receptor 4

Appendix B: General Information

- Per the Nerlynx prescribing information, antidiarrheal prophylaxis is recommended during the first 2 cycles (56 days) of Nerlynx treatment and should be initiated with the first dose of Nerlynx in order to address the risk of treatment discontinuation due to diarrhea, as was seen in the pivotal ExteNET trial.
- Nerlynx is FDA-approved for a one year total duration of therapy.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	240 mg PO QD	240 mg/day

VI. Product Availability

Tablets: 40 mg

VII. References

1. Nerlynx Prescribing Information. Los Angeles, CA: Puma Biotechnology, Inc.; July 2017. Available at: www.nerlynx.com. Accessed July 19, 2017.
2. Chan A, et al. Neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive breast cancer (ExteNET): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Oncology 2016;17:367-77.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.05.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.