

POLICY NUMBER UM_Onc_1316	SUBJECT Nerlynx™ (neratinib)	DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 07/26/17, 07/06/18, 06/12/19, 12/11/19, 04/08/20	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 07/26/17, 07/06/18, 06/12/19, 12/11/19, 04/08/20
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All

I. PURPOSE

To define and describe the accepted indications for Nerlynx (neratinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies: Error! Hyperlink reference not valid.**AND**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic alternatives are preferred over brand-name drugs.

2. Breast Cancer

- The member has early stage (stages I, II, and III) HER2 positive breast cancer and Nerlynx (neratinib) is being used as a single agent following completion of adjuvant trastuzumab of **ONE** year or less **OR**
- The member has metastatic HER2 positive metastatic breast cancer and Nerlynx (neratinib) is being used in combination with capecitabine and the member has received two or more prior anti-HER-2 based regimens except lapatinib in the metastatic setting.



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III. EXCLUSION CRITERIA

1. Nerlynx (neratinib) use after disease progression with the same regimen.
2. Dosing exceeds single dose limit of Nerlynx (neratinib) 240 mg.
3. Treatment exceeds the maximum 1year duration limit for the adjuvant setting, for early stage (stages I, II, and III) breast cancer.
4. Treatment exceeds the maximum limit of 180 (40 mg) tablets/month.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Nerlynx PI prescribing information. Puma Biotechnology, Inc. Los Angeles, CA 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.