Nerlynx (neratinib)
Effective 01/01/2021

Plan	☐ MassHealth ☒ MassHealth (PUF) ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Neratinib is an irreversible tyrosine kinase inhibitor of human epidermal growth factor receptor 1, 2, and 4 (HER1, HER2, and HER4), as well as epidermal growth factor receptor (EGFR). Neratinib reduces EGFR and HER2 autophosphorylation and downstream MAPK and AKT signaling pathways and demonstrates antitumor activity in EGFR and/or HER2 expressing cancer cell lines.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Nerlynx, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted if the member meets all following criteria and documentation has been submitted:

Adjuvant Therapy for Early Stage Disease*

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member received trastuzumab therapy within the past two years
5. Quantity requested is ≤ 6 units/day

Treatment of Metastatic Disease

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Inadequate response or adverse reaction to two anti-HER2-based regimens**
5. Requested agent will be used in combination with capecitabine
6. Quantity requested is ≤ 6 units/day

**Member is limited to one year total therapy with neratinib for adjuvant treatment.*
***Anti-HER2 directed therapies include Herceptin® (trastuzumab), Kadcyla® (ado-trastuzumab emtansine), and Perjeta® (pertuzumab). Please note that if these agents are used in combination (e.g., Herceptin® [trastuzumab] and Perjeta® [pertuzumab]), this would count as one regimen.*

Continuation criteria:
Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

Limitations
1. Authorizations will be granted approval for 12 months.
2. Adjuvant treatment of early stage breast cancer will be approved for a total of 12 months of therapy.
3. The following quantity limits apply:

Nerlynx 40mg	240 tablets per 30 days

References

1. Nerlynx [package insert]. Los Angeles, CA: Puma Biotechnology; February 2020.
2. Chan A, Delaloge S, Holmes FA, 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 Oncol. 2016; 17(3):367-77.
3. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed February 26, 2020.

Review History
02/2018 – Drug reviewed at P&T
03/18/20 – CVS added documentation requirement of HER2 status, where applicable. Removed metastatic CNS lesions as an approvable indication as the indication no longer meets the level of evidence. For continuation of therapy criteria, added requirement that there is no evidence of disease toxicity or disease progression.
05/20/20 – CVS added advanced or metastatic breast cancer in combination with capecitabine (Xeloda), per FDA label update.
10/2/20 – Effective 1/1/21: Updated criteria to be in compliance with Masshealth partial unified formulary requirements.

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