



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NERATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NERATINIB	NERLYNX	44421		GPI-10 (2153405810)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of early stage (stage I-III) breast cancer and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has a HER2-overexpressed/amplified (HER2-positive) tumor
- The tumor is hormone-receptor positive
- The requested medication will be used as extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
- The medication is being requested within 2 years after completing last trastuzumab dose

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180 per 30 days.**
If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has a HER2-overexpressed/amplified (HER2-positive) tumor
- The requested medication will be used in combination with capecitabine
- The patient has received two or more prior anti-HER2 based regimens in the metastatic setting

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180 per 30 days.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NERATINIB (Nerlynx)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Early stage (stage I-III) breast cancer
2. Advanced or metastatic breast cancer

B. **If you have early stage (stage I-III) breast cancer, approval also requires:**

1. You are 18 years of age or older
2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
3. The tumor is hormone-receptor positive
4. The requested medication will be used as extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
5. The medication is being requested within 2 years of completing the last trastuzumab dose

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GUIDELINES FOR USE (CONTINUED)

C. If you have advanced or metastatic breast cancer, approval also requires:

1. You are 18 years of age or older
2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
3. The requested medication will be used in combination with capecitabine
4. You have received two or more prior anti-HER2 based regimens in the metastatic setting

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nerlynx.

REFERENCES

- Nerlynx [Prescribing Information]. Los Angeles, CA: Puma Biotechnology; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/20

Created: 07/17

Client Approval: 03/20

P&T Approval: 04/20