STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NERATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NERATINIB MALEATE	NERLYNX	44421		GPI-10 (2153303510)	

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 requested medication will be used as a single agent for 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 requested medication will be used as a single agent for extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
      4. The medication is being requested within 2 years of completing the last trastuzumab dose

   (Denial text continued on next page)

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NERATINIB

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; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A　　Created: 07/17
Commercial Effective: 04/10/21　　Client Approval: 03/21　　P&T Approval: 04/20

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