



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAPATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAPATINIB DITOSYLATE	TYKERB, LAPATINIB	34541		GPI-10 (2153302610)	

GUIDELINES FOR USE

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

- The patient's breast cancer is human epidermal growth factor receptor 2 (HER2) positive
- The requested medication will be used in combination with Xeloda (capecitabine)
- The patient has received prior therapy with Herceptin (trastuzumab), an anthracycline (e.g., daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (e.g., paclitaxel, docetaxel)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per day.**

If no, continue to #2.

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

- The patient's breast cancer is human epidermal growth factor receptor 2 (HER2) positive
- The patient's tumor is hormone receptor-positive
- The requested medication will be used in combination with Femara (letrozole)
- The patient is a postmenopausal woman

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**

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 **LAPATINIB (Tykerb)** requires the following rule(s) be met for approval:

A. You have advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of your body)

B. Your breast cancer is human epidermal growth factor receptor 2 (HER2: gene/protein in breast cancer) positive

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

1. The requested medication will be used in combination with Xeloda (capecitabine)
2. You have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (such as paclitaxel, docetaxel)

D. **If you have metastatic breast cancer, approval also requires:**

1. Your tumor is hormone receptor-positive
2. The requested medication will be used in combination with Femara (letrozole)
3. You are a postmenopausal woman

(Denial text continued on the next page)

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GUIDELINES FOR USE (CONTINUED)

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 Tykerb.

REFERENCES

- Tykerb [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

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