LAPATINIB

Generic	Brand	HICL	GCN	Exception/Other
LAPATINIB DITOSYLATE	TYKERB	34541		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have breast cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's breast cancer HER2 positive (defined as IHC 3+ or FISH amplification ratio greater than 2.0)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the requested medication being used in combination with Xeloda (capecitabine), Herceptin (trastuzumab), or Femara (letrozole)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have estrogen or progesterone receptor-positive breast cancer?

   If yes, **approve for 12 months with a quantity limit of up to #6 per day per month.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, continue to #5.

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LAPATINIB

GUIDELINES FOR USE (CONTINUED)

5. Has the patient's prior therapy included Herceptin (trastuzumab)?

   If yes, **approve for 12 months with a quantity limit of up to #6 per day per month.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval criteria require concurrent treatment with Xeloda (capecitabine), Herceptin (trastuzumab), or Femara (letrozole) for patients with a diagnosis of HER2-positive breast cancer with estrogen/progesterone receptor-positive breast cancer; or a diagnosis of HER2-positive breast cancer in a patient with a previous trial of Herceptin (trastuzumab).

RATIONALE

To ensure that lapatinib is used in the appropriate patient population with HER2 positive breast cancer. Lapatinib in combination with capecitabine or trastuzumab is recommended for trastuzumab-exposed HER2 positive breast cancer. Lapatinib is recommended in combination with other chemotherapy for HER2 positive breast cancer that is either estrogen or progesterone receptor-positive or negative.

FDA APPROVED INDICATIONS

Tykerb is indicated in combination with:
Capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumors over express HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.
Letrozole, for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that over expresses the HER2 receptor for whom hormonal therapy is indicated.

REFERENCES

- GlaxoSmithKline. Tykerb package insert. Research Triangle Park, NC. April, 2010.
- National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer v.2.2011
- Thomson Healthcare. Monograph Name. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: June 27, 2011].

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAPATINIB

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/13
Created: 04/10
Client Approval: 08/13
P&T Approval: 08/13