



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: lapatinib

Brand Name: Tykerb

Medication Class: antineoplastic agent

FDA Approved Uses: Indicated in combination with capecitabine (Xeloda), 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.

Available Dosage Forms: 250mg tablets

Usual Dose: 1,250mg (5 tablets) by mouth once a day on Days 1-21 in combination with capecitabine (Xeloda) 2,000 mg/m² on days 1-14 in a repeating 21 day cycle.

Duration of Therapy: Until disease progression or unacceptable toxicity occurs.

Approximate monthly cost (based on AWP 2007): when given on days 1-21, cost is about \$2536.80.

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Must be prescribed by an oncologist.
- Clinically diagnosed advanced or metastatic breast cancer.
- Tumors must over express HER2.
- Must have received prior therapy including anthracycline, a taxane, and trastuzumab.
- Must be used in combination with Xeloda (capecitabine)

Monitoring:

- Potential cardiovascular toxicity.

Contraindications:

- None at this time.

Not Approved if:

- Does not meet the above stated criteria.

P&T Approval: _____ Date: _____