MEDICATION POLICY:
Tykerb®

Generic Name: Lapatinib

Therapeutic Class or Brand Name: Tykerb®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 2153405010

Preferred: Lapatinib

Non-preferred: Tykerb®

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/7/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:
   A. Advanced or metastatic HER2 positive breast cancer AND criteria 1 and 2 are met:
      1. Must be used in combination with capecitabine (Xeloda®).
      2. Documentation of prior therapy, including the following 3 agents listed a through c:
         a) An anthracycline (i.e. daunorubicin, doxorubicin, epirubicin, idarubicin, or valrubicin).
         b) A taxane (i.e. paclitaxel or docetaxel).
         c) Trastuzumab (Herceptin®, Ogivri™, Herzuma®).
   B. Hormone receptor positive, HER2 positive metastatic breast cancer AND criteria 1 and 2 are met:
      1. Patient is a postmenopausal woman.
      2. Must be used in combination with letrozole (Femara®).

II. Minimum age requirement: 18 years old.

III. Prescriber is an oncologist.

EXCLUSION CRITERIA

- N/A.

OTHER CRITERIA

- Use of Tykerb® with strong CYP3A4 inhibitors or inducers should be avoided. Exceptions may be made for higher doses (up to 660 tablets per 30 days) when concomitant use with CYP3A4 inducers (medications that decrease Tykerb® serum concentrations) cannot be avoided (see Appendix).

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities of up to 180 tablets per 30 days. See under Other Criteria for possible exceptions for higher doses (up to 660 tablets per 30 days).

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

Examples of Strong CYP3A4 Inducers (Reduce Tykerb® Serum Concentrations)

Carbamazepine (Tegretol®, Epitol®)	Phenytoin (Dilantin®)
Dexamethasone	Rifabutin (Mycobutin®)
Efavirenz (Sustiva®)	Rifapentine (Priftin®)
Nevirapine (Viramune®)	Rifampin (Rifadin®)
Phenobarbital	St. John's Wort

REFERENCES

1. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tykerb.pdf.
2. https://www.gene.com/download/pdf/xeloda_prescribing.pdf.
3. Medi-Span.
4. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?type=display&setid=6b7938e6-14c7-4a65-9605-967542ecfb8f.
5. https://www.nccn.org/patients/guidelines/content/PDF/stage_iv_breast-patient.pdf.