MEDICATION POLICY:
Tykerb®

Generic Name: Lapatinib

Therapeutic Class or Brand Name: Tykerb®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: Lapatinib

Non-preferred: Tykerb®

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/7/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V 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 3 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®, Herzuma®, Ogivri™, Ontruzant®, Trazimera™).
      3. Documentation of disease progression on Trastuzumab.
   B. Hormone receptor positive, HER2 positive metastatic breast cancer AND criteria 1 and 2 are met:
      1. Patient is a postmenopausal or premenopausal woman receiving ovarian ablation or suppression.
      2. Must be used in combination with letrozole (Femara®).

II. Minimum age requirement: 18 years old.

III. Treatment must be prescribed by or in consultation with an oncologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

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. Tykerb® Prescribing Information, East Hanover, NJ: Novartis. March 2022. Available at : https://www.novartis.com/us-en/sites/novartis_us/files/tykerb.pdf
2. Xeloda® Prescribing Information, San Francisco, CA: Genentech. May 2021. Available at: https://www.gene.com/download/pdf/xeloda_prescribing.pdf
3. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?type=display&setid=6b7938e6-14c7-4a65-9605-967542ecfb8f.
4. National Comprehensive Cancer Network (NCCN) Guidelines Breast Cancer. Version 4.2023, updated March 23, 2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast_blocks.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.