

Applicable Drugs: Tykerb (lapatinib)

Preferred: lapatinib (generic)

Non-preferred: Tykerb (brand)

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 2/27/2026

PRIOR AUTHORIZATION CRITERIA

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

- I. Documentation of the following FDA-approved diagnoses (A) AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication:

A. Breast Cancer

1. Documentation of advanced or metastatic disease
2. Documentation of human epidermal growth factor receptor 2 (HER2) positive disease and meets one of the following criteria a or b:
 - a) Used in combination with capecitabine (Xeloda)
 - a. Documentation of prior treatment with at least one medication from each of the following classes:
 - i. Anthracycline (i.e., daunorubicin, doxorubicin, epirubicin, idarubicin, or valrubicin)
 - ii. Taxane (i.e., paclitaxel or docetaxel)
 - b. Documentation of disease progression on trastuzumab (e.g., Herceptin, Hersuma, Kanjinti, Ogivri, Ontruzant, or Trazimera)
 - b) Used in combination with letrozole (Femara)
 - a. Documentation of hormone receptor positive disease
 - b. Documentation that patient is postmenopausal or pre- or peri-menopausal receiving ovarian ablation or suppression (e.g., leuprolide [Lupron] or goserelin [Zoladex])

Other Uses With Supportive Evidence

- B. Bone Cancer – Chordoma
- C. Breast Cancer – Invasive or Inflammatory
- D. Central Nervous System Cancers – Limited and Extensive Brain Metastases
- E. Colon Cancer
- F. Rectal Cancer

- 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 National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- 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

- Tablets: 250 mg
- Quantities are limited to a 30-day supply based on the following maximum doses:
 - Breast Cancer:
 - 1,250 mg orally once daily in combination with capecitabine (Xeloda)
 - 1,500 mg orally once daily in combination with letrozole (Femara)
- See Other Criteria for possible exceptions for higher doses.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

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. Novartis Pharmaceuticals Corporation. 2022. Accessed February 27, 2026. www.accessdata.fda.gov/drugsatfda_docs/label/2022/022059s031lbl.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast Cancer. Version 2.2026. Updated February 27, 2026. Accessed February 27, 2026. www.nccn.org/professionals/physician_gls/pdf/breast.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Bone Cancer. Version 2.2026. Updated December 19, 2025. Accessed February 27, 2026. www.nccn.org/professionals/physician_gls/pdf/bone.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 3.2025. Updated December 5, 2025. Accessed February 27, 2026. www.nccn.org/professionals/physician_gls/pdf/cns.pdf
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Colon Cancer. Version 5.2025. Updated October 30, 2025. Accessed February 27, 2026. www.nccn.org/professionals/physician_gls/pdf/colon.pdf
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Rectal Cancer. Version 4.2025. Updated October 31, 2025. Accessed February 27, 2026. www.nccn.org/professionals/physician_gls/pdf/rectal.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.