

Specialty Guideline Management

lapatinib-Tykerb

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tykerb	lapatinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications^{1,2}

Tykerb is indicated in combination with:

- Capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress human epidermal growth factor receptor 2 (HER2) and who have received prior therapy, including an anthracycline, a taxane, and trastuzumab.
- Letrozole for the treatment of postmenopausal women with hormone receptor (HR)-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.

Limitations of Use

Patients should have disease progression on trastuzumab prior to initiation of treatment with Tykerb in combination with capecitabine.

Reference number(s)
1902-A

Compendial Uses³⁻⁷

- Breast Cancer
- Chordoma
- Colorectal Cancer

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review, where applicable:

- Hormone receptor status
- HER2 status
- RAS and BRAF mutation status
- Epidermal growth factor receptor (EGFR) mutation status

Coverage Criteria

Breast Cancer¹⁻³

Authorization of 12 months may be granted for treatment of HER2- positive breast cancer when any of the following criteria are met:

- The requested medication will be used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane) with or without trastuzumab for HR-positive recurrent unresectable or metastatic disease.
- The requested medication will be used in combination with trastuzumab or capecitabine for recurrent unresectable, advanced, or metastatic disease or disease with no response to preoperative systemic therapy, as fourth line therapy and beyond.
- The requested medication will be used in combination with capecitabine for brain metastases.

Chordoma^{3,7}

Authorization of 12 months may be granted for treatment of EGFR-positive recurrent chordoma, as a single agent.

Reference number(s)
1902-A

Colorectal Cancer³⁻⁶

Authorization of 12 months may be granted for treatment of colorectal cancer (including appendiceal adenocarcinoma and anal adenocarcinoma) with HER2-amplified and RAS and BRAF wild-type disease in combination with trastuzumab when any of the following are met:

- The requested medication will be used as primary therapy if intensive therapy not recommended.
- The requested medication will be used as subsequent therapy for progression of advanced or metastatic disease not previously treated with a HER2 inhibitor.
- The requested medication will be used as initial therapy for unresectable metachronous metastases.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Tykerb [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2022.
2. Lapatinib [package insert]. Naples, FL: Lupin Pharmaceuticals, Inc.; June 2025.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed October 31, 2025.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Colon Cancer. Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed November 10, 2025.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf . Accessed November 10, 2025.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer. Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed October 31, 2025.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Bone Cancer. Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed October 29, 2025.