

SPECIALTY GUIDELINE MANAGEMENT

TYKERB (lapatinib)

POLICY

I. 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.

A. FDA-Approved Indications

Tykerb is indicated in combination with:

1. 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
2. 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

B. Compendial Uses

1. Recurrent or metastatic HER2-positive breast cancer in combination with trastuzumab
2. Recurrent or stage IV hormone receptor-positive, HER2-positive breast cancer in combination with aromatase inhibition in postmenopausal women
3. Central Nervous System (CNS) metastases from breast cancer
4. Recurrent epidermal growth factor receptor (EGFR)-positive chordoma

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Hormone receptor status, HER2 status, EGFR mutation testing results (where applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. **Breast cancer**

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

1. Tykerb is used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane) either with or without trastuzumab for the treatment of hormone receptor-positive disease; or
2. Tykerb will be used in combination with capecitabine or trastuzumab.

B. **Central nervous system metastases (CNS) from breast cancer**

Authorization of 12 months may be granted for the treatment of recurrent brain metastases from HER2-positive breast cancer in combination with capecitabine.

C. **Chordoma**

Reference number(s)
1902-A

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

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication in Section III who have not experienced disease progression or an unacceptable toxicity.

V. REFERENCES

1. Tykerb [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018.
2. The NCCN Drugs & Biologics Compendium 2019 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed August 14, 2019.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: breast cancer. Version 3.2018. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 16, 2019.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: central nervous system cancer. Version 2.2018. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 16, 2019.
5. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: bone cancer. Version 1.2019. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 16, 2019.