Reference number(s)
1902-A

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
5. HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with trastuzumab

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, RAS and BRAF mutation status, EGFR mutation testing results (where applicable).

III. CRITERIA FOR INITIAL APPROVAL

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

C. Chordoma

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

D. Colorectal Cancer

Authorization of 12 months may be granted for treatment of colorectal cancer with HER2-amplified and RAS and BRAF wild-type disease in combination with trastuzumab when either of the following are met:

1. Member is not appropriate for intensive therapy
2. Tykerb will be used as subsequent therapy for progression of advanced or metastatic disease.

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

1. Tykerb [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed December 2, 2020.