

lapatinib, oral (TYKERB)

Diagnosis Considered for Coverage:

- Advanced or metastatic Breast Cancer
- Advanced or metastatic colorectal cancer
- Bone Cancer – Chordoma

Coverage Criteria:

For diagnosis of breast cancer:

- Patient is positive for Human Epidermal growth factor Receptor 2 (HER2) over-expression, **and**
- One of the following:
 - Being used in combination with an aromatase inhibitor (e.g. anastrozole, exemestane, letrozole), **or**
 - Patient has received 2 prior therapies (third line or beyond) **AND** being used in combination with either capecitabine (Xeloda)/5-FU or trastuzumab (Herceptin), **or**
 - Patient has brain metastases **AND** being used in combination with capecitabine

AND

- Dose does not exceed FDA or compendium labeled maximum

For diagnosis of advanced, unresectable, or metastatic colorectal cancer:

- Disease is considered unresectable, advanced or metastatic, **and**
- Patient is positive for Human Epidermal growth factor Receptor 2 (HER2) over-expression, **and**
- Patient does NOT have KRAS/NRAS gene mutation, **and**
- Patient has NOT received prior treatment with a HER2 inhibitor (e.g. lapatinib, trastuzumab, neratinib), **and**
- Being used in combination with Herceptin (trastuzumab), **and**
- Dose does not exceed 1500 mg per day.

For diagnosis of chordoma:

- Patient has recurrent conventional or chondroid chordoma, **and**
- Patient is EGFR mutation positive, **and**
- Being used as single agent therapy, **and**
- Dose does not exceed 1500 mg per day.

Coverage Duration: one year

Effective Date: 09/27/2023