PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE:	**3/17/2016**
LAST REVIEW DATE:	**2/17/2022**
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Lapatinib oral
TYKERB® (lapatinib) oral

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy**: Tykerb (lapatinib) and generic Lapatinib are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     a. Combination therapy 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

     b. Combination therapy with letrozole for the treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated

     c. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  4. **ALL** of the following baseline tests have been completed before initiation of treatment:
     a. Negative pregnancy test in a woman of childbearing age
     b. Liver function tests (transaminases, bilirubin, and alkaline phosphatase)
     c. Left ventricular ejection fraction (LVEF) evaluation using an echocardiogram, multi-gated acquisition scan, or other appropriate test that shows LVEF is within normal limits
     d. Serum potassium and magnesium are within normal limits

  5. There are no significant interacting drugs

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request)**: Tykerb (lapatinib) and generic Lapatinib are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual's condition has responded while on therapy
     a. Response is defined as:
        i. Documented evidence of efficacy, disease stability and/or improvement

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ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

3. Individual has been adherent with the medication

4. Individual has not developed any significant adverse drug effects that may exclude continued use
   a. Significant adverse effect such as:
      i. A moderate or greater decrease in left ventricular ejection fraction below the institution's normal limits
      ii. Severe hepatic impairment
      iii. Severe diarrhea requiring oral or intravenous electrolytes and fluids, use of antibiotics or life-threatening diarrhea
      iv. Interstitial lung disease or pneumonitis
      v. Cutaneous reactions such as erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis

5. There are no significant interacting drugs

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Tykerb (lapatinib) is indicated in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress human epidermal receptor type 2 (HER2) and who have received prior therapy including an anthracycline, a taxane, and trastuzumab; and in combination with letrozole for the treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.

Patients should have disease progression on trastuzumab prior to initiation of treatment with Tykerb (lapatinib) in combination with capecitabine. Tykerb (lapatinib) in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer.

Tykerb (lapatinib) is a kinase inhibitor of both epidermal growth factor receptor (EGFR) and of HER2 receptors. Lapatinib inhibits tumor cell growth *in vitro* and in various animal models.

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Resources:

Tykerb (lapatinib) product information, revised by Novartis Pharmaceuticals Corporation 12-2018. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 08, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Breast Cancer Version 1.2022 – Updated November 24, 2021. Available at https://www.nccn.org. Accessed December 08, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.