BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

**PHARMACY COVERAGE GUIDELINE**

# Erlotinib oral
# TARCEVA® (erlotinib) oral

**This Pharmacy Coverage Guideline (PCG):**
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

**Scope**
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

**Instructions & Guidance**
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

## Criteria:

➢ **Criteria for initial therapy:** Tarceva (erlotinib) or erlotinib generic is considered ***medically necessary*** and will be approved when **ALL** 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. Individual has a confirmed diagnosis of **ONE** of the following:
    a. Metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth-factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutations receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen

b. First-line treatment of pancreatic cancer (locally advanced, unresectable or metastatic) in combination with gemcitabine

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. **For brand Tarceva (erlotinib),** documented failure, contraindication per FDA label, intolerance to or not a candidate for generic erlotinib.

5. Eastern Cooperative Oncology Group (ECOG) Performance Status is 0-1.

**Initial approval duration**: 6 months

- **Criteria for continuation of coverage (renewal request):** Tarceva (erlotinib) or erlotinib generic is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy**):

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 with response defined as **ALL** of the following:
   a. No evidence of disease progression
   b. Documented evidence of efficacy, disease stability and/or improvement

3. Individual has been adherent with the medication.

4. For continuation of **brand Tarceva (erlotinib)**, documented failure, contraindication per FDA label, intolerance to or not a candidate for generic erlotinib.

5. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
   a. Confirmed interstitial lung disease
   b. Severe hepatotoxicity
   c. Gastrointestinal perforation
   d. Severe bullous, blistering or exfoliating skin conditions
   e. Corneal perforation, severe ulceration, or persistent severe keratitis
   f. Severe renal dysfunction

**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**

**PHARMACY COVERAGE GUIDELINE**

# Erlotinib oral
# TARCEVA® (erlotinib) oral

## 2. Off-Label Use of Cancer Medications

**Description:**

Erlotinib (brand Tarceva or generic) is a kinase inhibitor that is indicated for the treatment of patients with metastatic **non-small cell lung cancer (NSCLC)** whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen and as first-line treatment of locally advanced, unresectable or metastatic **pancreatic cancer**, used in combination with gemcitabine. Erlotinib (brand or generic) is not recommended for use as a component of a therapeutic regimen that will include combination with platinum-based chemotherapy. The safety and efficacy of erlotinib (brand or generic) have not been evaluated as first-line treatment in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution.

EGFR is expressed on the cell surface of both normal and cancer cells. In some cancer cells signaling through this receptor plays a role in cancer cell survival and proliferation. Erlotinib reversibly inhibits the kinase activity of EGFR, preventing phosphorylation of tyrosine residues associated with the receptor and thereby inhibiting further downstream signaling. The binding affinity of erlotinib for EGFR exon 19 deletion or exon 21 (L858R) mutations is higher than its affinity for the wild type receptor. erlotinib inhibition of other tyrosine kinase receptors has not been fully characterized.

**Resources:**

Tarceva (erlotinib) product information, revised by Genentech, Inc. 10-2016. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 06, 2022.

Erlotinib product information, revised by Teva Pharmaceuticals USA, Inc. 10-2017. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 06, 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-Small Cell Lung Cancer Version 3.2022 – Updated March 16, 2022. Available at https://www.nccn.org. Accessed August 06, 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Pancreatic Adenocarcinoma Version 1.2022 – Updated February 24, 2022. Available at https://www.nccn.org. Accessed August 06, 2022.

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.