



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/01/2016
LAST REVIEW DATE: 8/19/2021
LAST CRITERIA REVISION DATE: 8/19/2021
ARCHIVE DATE:

TARCEVA® (erlotinib) 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.

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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:** Tarceva (erlotinib) is 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. 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. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
 - a. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1
 5. There are no significant interacting drugs

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Tarceva (erlotinib) is considered *medically necessary* and will be approved with documentation of **ALL** of the following:
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 responded while on therapy
 - a. Response is defined as:
 - i. No evidence of disease progression
 - ii. Documented evidence of efficacy, disease stability and/or improvement
 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. Confirmed interstitial lung disease
 - ii. Severe hepatotoxicity



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- iii. Gastrointestinal perforation
- iv. Severe bullous, blistering or exfoliating skin conditions
- v. Corneal perforation, severe ulceration, or persistent severe keratitis
- vi. Severe renal dysfunction

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 a Non-cancer Medications**
2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Tarceva (erlotinib) 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.** Tarceva (erlotinib) 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 Tarceva (erlotinib) 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.



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Resources:

Tarceva (erlotinib) product information, revised by Genentech, Inc. 10-2017. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed on June 28, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-Small Cell Lung Cancer Version 5.2021 – Updated June 15, 2021. Available at <https://www.nccn.org>. Accessed on June 23, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Pancreatic Adenocarcinoma Version 2.2021 – Updated February 25, 2021. Available at <https://www.nccn.org>. Accessed on June 28, 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.
