BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**1/01/16**
LAST REVIEW DATE:	**9/20/18**
LAST CRITERIA REVISION DATE:	**9/20/18**
ARCHIVE DATE:	

TARCEVA® (erlotinib) oral tablet

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.**

TARCEVA® (erlotinib) oral tablet (cont.)

Criteria:

- **Criteria for initial therapy:** Tarceva is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is an Oncologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     - First-line treatment of metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 (L858R) substitution
     - Second line or greater treatment of metastatic NSCLC with EGFR exon 19 deletion or exon 21 (L858R) substitution after progression following at least one prior chemotherapy
     - Maintenance of metastatic NSCLC with EGFR exon 19 deletion or exon 21 (L858R) substitution whose disease has not progressed after platinum based first-line therapy
     - First-line treatment of pancreatic cancer (locally advanced, unresectable or metastatic) in combination with gemcitabine
     - 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, 2A, or 2B

  4. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     - Comprehensive metabolic panel

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Tarceva is considered ***medically necessary*** and will be approved with documentation of **ALL** of the following:

  1. Continues to be seen by an Oncologist

  2. The cancer has not progressed while on therapy

  3. Individual has been adherent with the medication

  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use, such as:
     - Confirmed interstitial lung disease
     - Severe hepatotoxicity
     - Gastrointestinal perforation

TARCEVA® (erlotinib) oral tablet (cont.)

- Severe bullous, blistering or exfoliating skin conditions
- Corneal perforation, severe ulceration, or persistent severe keratitis
- Severe renal dysfunction

5. There are no significant interacting drugs

Renewal duration: 12 months

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.

Resources:

Tarceva. Package Insert. Revised by manufacturer 04/2015. Accessed 08-04-2015.

Tarceva. Package Insert. Revised by manufacturer 06/2016. Accessed 07-22-2016.

Tarceva. Package Insert. Revised by manufacturer 10/2016. Accessed 07-25-2017, 07-19-2018.

NCCN Clinical Practice Guidelines in Oncology: Non-small cell lung cancer. Version 8.2017, July 14, 2017. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf

NCCN Clinical Practice Guidelines in Oncology: Non-small cell lung cancer. Version 6.2018, Aug 17, 2018. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf

TARCEVA® (erlotinib) oral tablet (cont.)

NCCN Clinical Practice Guidelines in Oncology: Pancreatic adenocarcinoma. Version 2.2017, April 27, 2017. https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf

NCCN Clinical Practice Guidelines in Oncology: Pancreatic adenocarcinoma. Version 2.2018, July 10, 2018. https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf

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.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:		Dosage Form:
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.