BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**1/21/16**
LAST REVIEW DATE:	**8/02/18**
LAST CRITERIA REVISION DATE:	**8/02/18**
ARCHIVE DATE:	

TAGRISSO™ (osimertinib) 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.**

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Criteria:

- **Criteria for initial therapy:** Tagrisso (osimertinib) 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 metastatic non-small cell lung cancer (NSCLC) with **ONE** of the following:
     - Patients whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions **or** exon 21 L858R mutations, to be used as first-line treatment
     - Patients with EGFR T790M mutation-positive tumor, who have progressed on or after EGFR TKI therapy
       - EGRF TKI therapy includes:
         - Gilotrif (afatinib)
         - Iressa (gefitinib)
         - Tarceva (erlotinib)
  4. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     - FDA-approved test confirming the presence of exon deletions or mutation in tumor specimens
     - Left ventricular ejection fraction (LVEF) by echocardiogram or multigated acquisition scan
     - Electrocardiogram
     - Comprehensive metabolic panel
     - Pregnancy test in a woman of reproductive potential
  5. Will not be used in a patient with end-stage renal disease (CrCl < 15 mL/min)
  6. Will not be used in a patient with severe hepatic impairment (total bilirubin > 3x ULN and any AST value)
  7. Woman patient of child bearing age should use effective contraception during and for 6 weeks after therapy
  8. Woman patient who is breast feeding an infant or child should stop breast feeding during and for 2 weeks after therapy
  9. Male patient with a female partner of child bearing age should use effective contraception during and for 4 months after therapy

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Tagrisso (osimertinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

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1. Individual continues to be seen by an Oncologist

2. Individual's condition responded while on therapy
   - Response is defined as:
     - No evidence of disease progression
     - 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 level 4 adverse drug effects that may exclude continued use
   - Significant adverse effect such as:
     - Interstitial Lung Disease/Pneumonitis
     - Symptomatic heart failure or QTc prolongation with life-threatening arrhythmia
     - Any adverse effect that does not improve within 3 weeks of dose mondification

5. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Tagrisso (osimertinib) is a kinase inhibitor indicated for the first-line 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 mutations, as detected by an FDA-approved test and for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

Osimertinib is kinase inhibitor of the EGFR, which binds irreversibly to certain mutant forms of EGFR (T790M, L858R, and exon 19 deletion). It exhibits anti-tumor activity against NSCLC lines harboring EGFR-mutations (T790M/L858R, L858R, T790M/exon 19 deletion, and exon 19 deletion) and to a lesser extent, wild-type EGFR amplifications.

Lung cancer:

- Lung cancer is the second most common cancer in the United States and it is the leading cause of cancer-related mortality

- There are two main types of lung cancer:
  - Small cell lung cancer (SCLC)
    - SCLC is also known as "oat-cell" cancer because the cells look like oats under the microscope
  - Non-small cell lung cancer (NSCLC)
    - NSCLC is the most common type of lung cancer and is seen in 85-90% of lung cancers
    - NSCLC can be either squamous or non-squamous type

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- Classification:
  - Adenocarcinoma
  - Adenosquamous carcinoma
  - Large-cell undifferentiated carcinoma
  - Sarcomatoid carcinoma which includes pleomorphic carcinoma, carcinosarcoma, and pulmonary blastoma
  - Squamous cell carcinoma
    - Squamous (epidermoid) cells are thin, flat cells that look like fish scales
    - Squamous cells are seen in the tissues that line the larger airways
- Non-squamous cancers usually begin in more distal airway

- Distribution of various NSCLC types:
  - About 40% of lung cancers are adenocarcinomas
  - About 25-30% of lung cancers are squamous cell carcinomas
  - About 10-15% of lung cancers are large cell undifferentiated carcinomas

- Brain metastases are a frequent complication of NSCLC, with 25-40% of patients developing brain metastases during the course of the disease
  - Many patients with brain metastases are not eligible for radiation therapy due to poor performance status

- An estimated 2-7% NSCLC are found to have ALK gene rearrangements and 15% of NSCLC cases have epidermal growth factor receptor (EGFR) mutations
  - ALK rearrangements and sensitizing EGFR mutations are generally mutually exclusive
  - Central nervous system progression is common with ALK gene rearrangements and accounts for significant morbidity and mortality among these patients
  - Individuals who are relatively young, never or light smokers with adenocarcinoma are most likely to have ALK gene rearrangements

NCCN Drugs and Biologics Compendium, accessed 07-18-18

Non-Small Cell Lung Cancer - NSCLC with Adenocarcinoma (with mixed subtypes); Squamous cell carcinoma; Large cell carcinoma: (NCCN Version 5.2018, June 27, 2018.)

Tagrisso (osimertinib) as single-agent therapy for sensitizing EGFR mutation-positive recurrent or metastatic disease as:

- First-line therapy
- Subsequent therapy for EGFR T790M mutation-positive disease following progression on erlotinib, afatinib, or gefitinib
- Continuation of therapy following disease progression on osimertinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions

– NCCN Category 1 for first-line therapy if EGFR mutation discovered prior to first-line chemotherapy, for subsequent therapy following progression on erlotinib, afatinib, or gefitinib

– NCCN Category 2A for all others

– NCCN Category 2B for locoregional recurrence (excluding mediastinal lymph node recurrence with prior radiation therapy) with no evidence of disseminated disease

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Central Nervous System Cancers with limited or extensive metastasis: (NCCN Version 1.2018, March 20, 2018)
Tagrisso (osimertinib) as single-agent treatment for recurrent brain metastases in patients with EGFR T790M mutation-positive NSCLC and stable systemic disease or reasonable systemic treatment options – NCCN Category 2A

Resources:

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.

Tagrisso. Package Insert. Reference ID 3180800. Revised by manufacturer 11/2015. Accessed 01-26-2016.

Tagrisso. Package Insert. Revised by manufacturer 09/2016. Accessed 12-01-2016.

Tagrisso. Package Insert. Revised by manufacturer 10/2017. Accessed 12-25-2017.

NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 2.2018, Dec 19, 2017. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf

NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 5.2018, June 27, 2018. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf

NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Version 1.2018, March 20, 2018. https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

Tagrisso (osimertinib) product information accessed 07-18-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e81b4a7-b971-45e1-9c31-29cea8c87ce7

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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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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.