BlueCross BlueShield Arizona

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PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
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TAGRISSO™ (osimertinib)

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 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. Non-small cell lung cancer (NSCLC) with **ONE** of the following:
        i. Adjuvant therapy after tumor resection whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations

        ii. First-line treatment of metastatic tumors that have epidermal growth factor receptor (EGFR) exon 19 deletions **or** exon 21 L858R mutations

        iii. Treatment of metastatic EGFR T790M mutation-positive tumor, who have progressed on or after Gilotrif (afatinib), Vizimpro (dacomitinib), Tarceva (erlotinib), or Iressa (gefitinib)

     b. 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. FDA-approved test confirming the presence of exon deletions or mutation in tumor specimens
     b. Left ventricular ejection fraction (LVEF) by echocardiogram or multigated acquisition scan
     c. A negative pregnancy test in a woman of reproductive potential
     d. Eastern Cooperative Oncology Group Performance status of 0-1

  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)

  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:

  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:

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i. No evidence of disease progression
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. Will not be used in a patient with end-stage renal disease (CrCl < 15 mL/min)

5. Will not be used in a patient with severe hepatic impairment (total bilirubin > 3x ULN and any AST value)

6. Individual has not developed any significant adverse drug effects that may exclude continued use
   a. Significant adverse effect such as:
      i. Interstitial Lung Disease/Pneumonitis
      ii. Symptomatic heart failure or QTc prolongation with life-threatening arrhythmia
      iii. Symptomatic congestive heart failure
      iv. Erythema Multiforme or Stevens-Johnson Syndrome
      v. Cutaneous Vasculitis
      vi. Any adverse effect that does not improve within 3 weeks of dose modification

7. 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:

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.

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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
    - 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

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Definitions:

NCCN Non-Small Cell Lung Cancer Guideline Version 4.2021:
Therapy for sensitizing EGFR mutation positive tumor:

- First-line therapy:
  - Gilotrif (afatinib)
  - Vizimpro (dacomitinib)
  - Tarceva (erlotinib)
  - Iressa (gefitinib)
  - Tagrisso (osimertinib)
  - Tarceva (erlotinib) plus Cyramza (ramucirumab, intravenous)
  - Tarceva (erlotinib) plus bevacizumab intravenous (nonsquamous)
- Subsequent therapy:
  - Tagrisso (osimertinib)

Resources:

Tagrisso (osimertinib) product information, revised by AstraZenica Pharmaceuticals LP 01-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 13, 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 May 13, 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.