BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**1/01/2016**
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GILOTRIF™ (afatinib) 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:** Gilotrif (afatinib) 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 non-resistant epidermal growth factor receptor (EGFR) mutations

     b. Metastatic squamous NSCLC progressing after platinum-based chemotherapy

     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. Positive for non-resistant epidermal growth factor receptor (EGFR) mutation
     b. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1

  5. Individual does not have There are no significant interacting drugs end-stage renal disease (estimated glomerular filtration rate of less than 15 mL/min/1.73 m^2) or on dialysis

  6. Individual does not have severe hepatic disease (Child-Pugh Class C)

  7. There are no significant interacting drugs

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Gilotrif (afatinib) 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:
        i. Documented evidence of efficacy, disease stability and/or improvement
        ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

GILOTRIF™ (afatinib) oral tablet

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use such as:
    a. Life-threatening bullous, blistering, or exfoliative skin lesions including toxic epidermal necrolysis (TEN) and Stevens Johnson syndrome (SJS)
    b. Confirmed interstitial lung disease
    c. Severe hepatic impairment
    d. Gastrointestinal perforation
    e. Persistent ulcerative keratitis
    f. Symptomatic left ventricular dysfunction
    g. Severe or intolerable adverse reaction occurring at a dose of 20 mg per day

5. Individual does not have There are no significant interacting drugs end-stage renal disease (estimated glomerular filtration rate of less than 15 mL/min/1.73 m^2) or on dialysis

6. Individual does not have severe hepatic disease (Child-Pugh Class C)

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:

Gilotrif (afatinib) is a tyrosine kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test and it is indicated for the treatment of patients with metastatic squamous NSCLC progressing after platinum-based chemotherapy.

Afatinib covalently binds to the kinase domains of EGFR (ErbB1), HER2 (ErbB2), and HER4 (ErbB4) and irreversibly inhibits tyrosine kinase autophosphorylation, resulting in downregulation of ErbB signaling. Treatment with afatinib results in inhibition of tumor growth.

There are two main types of lung cancer: small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC). SCLC is also known as “oat-cell” cancer because the cells look like oats under the microscope. NSCLC is the most common type of lung cancer, seen in 85-90% of lung cancers. NSCLC can be divided histopathologically as either squamous or non-squamous type. Squamous (epidermoid) cells are thin, flat cells that look like fish scales

and are seen in the tissues that line the larger airways where as non-squamous cancers usually begin in more distal airway. There are three main types of NSCLC: squamous cell carcinoma; adenocarcinoma; and large-cell undifferentiated carcinoma. About 25-30% of all lung cancers are squamous cell carcinomas, 40% are adenocarcinomas, and large cell (undifferentiated) carcinoma accounts for about 10-15% of lung cancers.

Resources:

Gilotrif (afatinib) product information, revised by Boehringer Ingelheim Pharmaceuticals, Inc. 10-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 03, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-Small Cell Lung Cancer Version 7.2021 – Updated October 29,2021. Available at https://www.nccn.org. Accessed November 29,2021.

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.