BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 1/21/2016**
SECTION: DRUGS	**LAST REVIEW DATE: 2/17/2022**
	LAST CRITERIA REVISION DATE: 2/17/2022
	ARCHIVE DATE:

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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:** Alecensa (alectinib) 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. Anaplastic lymphoma kinase (ALK)-positive recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test for **any** of the following:
        i. As a preferred first-line therapy
        ii. As an option for patients who are intolerant to crizotinib
        iii. As an optional subsequent therapy following disease progression on first-line therapy with crizotinib except in cases of symptomatic systemic disease with an isolated lesion
        iv. As continuation of therapy if used first line, except in cases of symptomatic systemic disease with multiple lesions

     b. Single-agent treatment for brain metastases (limited and extensive) in patients with ALK rearrangement-positive NSCLC

     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:
     a. Liver enzyme tests (alanine transaminase (ALT), aspartate transaminase (AST), and total bilirubin)
     b. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2

  5. There are no significant interacting drugs

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Alecensa (alectinib) 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 by an Oncologist

  2. Individual's condition has responded while on therapy
     a. Response is defined as:
        i. Documented evidence of efficacy, disease stability and/or improvement

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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. Requested dose is at least 300 mg twice daily

5. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
   a. Significant adverse effects include:
      i. Hepatotoxicity
      ii. Interstitial lung disease/Pneumonitis
      iii. Renal impairment
      iv. Bradycardia (life-threatening consequences, urgent intervention needed)
      v. Hemolytic anemia

6. 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:

Alecensa (alectinib) is a tyrosine kinase inhibitor that is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC).

Alectinib binds to and inhibits ALK kinase. Inhibition leads to disruption of ALK-mediated signaling and eventually inhibits tumor cell growth in ALK-overexpressing tumor cells. ALK belongs to the insulin receptor superfamily and plays an important role in nervous system development. ALK dysregulation and gene rearrangements are associated with a series of tumors.

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

Resources:

Alecensa (alectinib) product information, revised by Genentech, Inc. 09-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 29, 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.

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National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Central Nervous System Cancers Version 2.2021 – Updated September 08, 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.