BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/19/2020
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

GAVRETO™ (pralsetinib) oral

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.**

GAVRETO™ (pralsetinib) oral

Criteria:

- **Criteria for initial therapy:** Gavreto (pralsetinib) 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) that is metastatic, rearranged during transfection (RET) fusion-positive
     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. Individual has an Eastern Cooperative Oncology Group (ECOG) Performance Status score of 2 or less
  5. Individual does not have moderate or severe hepatic impairment (total bilirubin greater than 2.5 times the upper limit of normal with any value of aspartate aminotransferase)
  6. Individual does not have severe renal impairment (CLcr of less than 15 mL/min)

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Gavreto (pralsetinib) 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 has not worsened while on therapy.
     a. Worsening is defined as:
        i. Disease progressed while on Gavreto
        ii. There is no evidence of efficacy, disease stability and/or improvement
  3. Individual has been adherent with the medication
  4. Individual is using at least 100 mg daily
  5. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
     a. Adverse effects such as:
        i. Interstitial Lung Disease
        ii. Pneumonitis

GAVRETO™ (pralsetinib) oral

iii. Uncontrolled hypertension despite medical therapy
iv. Hepatotoxicity
v. Hemorrhagic events

6. There are no significant interacting drugs

Renewal duration: 12 months

- Gavreto (pralsetinib) for all other indications not previously listed is considered ***experimental or investigational*** and will not be covered when any one or more of the following criteria are met:
  1. Lack of final approval from the Food and Drug Administration;
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes;
  3. Insufficient evidence to support improvement of the net health outcome;
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; **or**
  5. Insufficient evidence to support improvement outside the investigational setting.

  These indications include, but are not limited to:
  - Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration.

Description:

Gavreto (pralsetinib) is a kinase inhibitor indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test.

This indication is approved under accelerated approval based on overall response rate and duration of response.

Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Resources:

Gavreto (pralsetinib) product information, revised by manufacturer Blueprint Medicines Corporation 09-2020, at DailyMed http://dailymed.nlm.nih.gov. Accessed October 13, 2020.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-Small Cell Lung Cancer Version 8.2020 – Updated September 15, 2020 ; https://www.nccn.org. Accessed October 13, 2020.

GAVRETO™ (pralsetinib) oral

Sequist LV, Neal JW. Personalized, genotype-directed therapy for advanced non-small cell lung cancer. In: UpToDate, Lilenbaum RC, Vora SR (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on October 15, 2020.

Lilenbaum RC. Overview of the initial treatment of advanced non-small cell lung cancer. In: UpToDate, West H, Vora SR (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on October 15, 2020.

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.