



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/19/2020
LAST REVIEW DATE: 11/18/2021
LAST CRITERIA REVISION DATE: 11/18/2021
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.

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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:** 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. A confirmed diagnosis of **ONE** of the following:
 - a. Individual is 18 years of age or older with non-small cell lung cancer (NSCLC) that is metastatic, rearranged during transfection (RET) fusion-positive
 - b. Individual is 12 years of age or older with advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC) who require systemic therapy
 - c. Individual is 12 years of age or older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)
 - d. 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
 3. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
 - a. Negative pregnancy test in a woman of childbearing potential
 - b. Individual has an Eastern Cooperative Oncology Group (ECOG) Performance Status score of 2 or less
 4. Individual does not have moderate or severe hepatic impairment (total bilirubin greater than 1.5 times the upper limit of normal with any value of aspartate aminotransferase)
 5. Individual does not have severe renal impairment (CrCl of less than 15 mL/min)
 6. There are no significant interacting drugs

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:



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- i. Disease progression
 - 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 adverse drug effects that may exclude continued use
 - a. Adverse effects such as:
 - i. Interstitial Lung Disease
 - ii. Pneumonitis
 - iii. Uncontrolled hypertension despite medical therapy
 - iv. Hepatotoxicity
 - v. Hemorrhagic events
 - vi. Growth abnormalities in a pediatric patient with open growth plates
6. Individual does not have moderate or severe hepatic impairment (total bilirubin greater than 1.5 times the upper limit of normal with any value of aspartate aminotransferase)
7. Individual does not have severe renal impairment (CrCl of less than 15 mL/min)
8. 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 a Non-cancer Medications**
2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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. It is also indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy or for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).



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These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Resources:

Gavreto (pralsetinib) product information, revised by manufacturer Genentech, Inc. 04-2021. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed August 30, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-Small Cell Lung Cancer Version 5.2021 – Updated June 15, 2021. Available at <https://www.nccn.org>. Accessed August 30, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Thyroid Carcinoma Version 1.2021 – Updated April 09, 2021. Available at <https://www.nccn.org>. Accessed August 30, 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.
