UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1336-5
Program	Prior Authorization/Notification
Medication	Gavreto® (pralsetinib)
P&T Approval Date	11/2020, 11/2021, 11/2022, 11/2023, 11/2024
Effective Date	2/15/2025

1. Background:

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).

Gavreto is also indicated for 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). 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). The National Cancer Comprehensive Network (NCCN) also recommends use of Gavreto in hepatobiliary cancers that is RET gene fusion positive.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Gavreto** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Non-Small Cell Lung Cancer (NSCLC)</u>

1. **<u>Initial Authorization</u>**

   a. **Gavreto** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Disease is **one** of the following:

(a) Recurrent
(b) Advanced
(c) Metastatic

-AND-

(3) Presence of RET rearrangement positive tumors

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Gavreto** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Gavreto therapy

Authorization will be issued for 12 months.

B. Thyroid Carcinoma

1. **Initial Authorization**

a. **Gavreto** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of **one** of the following:

i. Follicular carcinoma
ii. Oncocytic carcinoma
iii. Papillary carcinoma

-AND-

(b) **One** of the following:

i. Unresectable locoregional recurrent disease
ii. Persistent disease
iii. Metastatic disease

-AND-

(c) Disease is RET gene-fusion positive

-AND-

(d) Disease is not amenable to radioactive iodine therapy

-OR-

(2) **All** of the following:

(a) Diagnosis of medullary carcinoma

-AND-

(b) **One** of the following:

i. Disease is recurrent, persistent, or progressive
ii. Disease is symptomatic with distant metastases

-AND-

(c) Disease is RET-mutation positive

-OR-

(3) **All** of the following:

(a) Diagnosis of anaplastic carcinoma

-AND-

(b) **One** of the following:

i. Disease is stage IVA or IVB (locoregional)
ii. Disease is metastatic

-AND-

(c) Disease is RET gene fusion positive

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Gavreto** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Gavreto therapy

Authorization will be issued for 12 months.

C. Hepatobiliary Cancers

1. **Initial Authorization**

a. **Gavreto** will be approved based on **both** of the following criteria:

(1) **One** of the following:

(a) **Both** of the following:

i. Diagnosis of gallbladder cancer

-AND-

ii. Disease is **one** of the following
- Unresectable
- Resected gross residual (R2)
- Metastatic

-OR-

(b) **Both** of the following:

i. Diagnosis of cholangiocarcinoma

-AND-

ii. Disease is **one** of the following
- Unresectable
- Resected gross residual (R2)
- Metastatic
- Resectable locoregionally advanced

-AND-

(2) Disease is positive for RET gene fusion mutation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Gavreto will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Gavreto therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Gavreto [package insert]. South San Francisco, CA: Blueprint Medicines Corporation, March 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed September 29, 2024.

Program	Prior Authorization/Notification – Gavreto® (pralsetinib)
Change Control	
11/2020	New program.
11/2021	Annual review. Added criteria for thyroid carcinoma according to label and NCCN compendium. Updated background and references.
11/2022	Annual review. Updated coverage criteria to include hepatobiliary cancers per NCCN compendium. Added state mandate and updated references.
11/2023	Annual review. Updated NSCLC criteria based on FDA label. Updated hepatobiliary cancer criteria per NCCN compendium. Updated name of oncocytic carcinoma per NCCN nomenclature. Updated references.
11/2024	Annual review. Updated criteria for hepatobiliary cancers based on NCCN guideline. Updated reference.