UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Gavreto

Program	Prior Authorization- Gavreto
Medication	Gavreto™ (pralsetinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	11/2020
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

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).

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) guideline also recommends use of Gavreto as preferred single-agent therapy for recurrent, advanced, or metastatic disease in patients with RET rearrangement positive tumors.

2. Coverage Criteria:

A. Non-Small Cell Lung Cancer (NSCLC)

1. Initial Authorization

a. Gavreto will be approved based on **all** 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* gene fusion-positive or *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. NCCN Recommended Regimens

1. **Initial Authorization**

a. **Gavretol** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Gavreto therapy

Authorization will be issued for 12 months.

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.

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4. References:

1. Gavreto [package insert]. Cambridge, MA: Blueprint Medicines Corporation, September 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed October 7, 2020.

Program	Prior Authorization– Gavreto™ (pralsetinib)
Change Control	
Date	Change
11/2020	New program