

Gavreto (pralsetinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Gavreto (pralsetinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Gavreto (pralsetinib) may be approved if the following criteria are met:

- I. Individual has recurrent, advanced, or metastatic Non-Small Cell Lung Cancer (NSCLC) (Label, NCCN 2A); **AND**
 - A. Individual is using as monotherapy; **AND**
 - B. Individual has confirmation of RET fusion (or rearrangement) positive tumors; **AND**
 - C. Individual has not received treatment with another RET rearrangement positive-targeted agent, such as cabozantinib, vandetanib, or selpercatinib (NCT03037385);

OR

- II. Individual has resectable, locoregionally advanced gallbladder cancer (NCCN 2A); **AND**
 - A. Individual has confirmation of RET fusion positive tumor; **AND**
 - B. Individual is using as a single agent in neoadjuvant therapy; **AND**
 - C. Individual does not present with jaundice;

OR

- III. Individual has unresectable, recurrent, advanced, or metastatic (non-medullary) Thyroid Cancer (Label, NCCN 2A); **AND**
 - A. Individual is 12 years of age or older; **AND**
 - B. Individual is using as monotherapy; **AND**
 - C. Individual has confirmation of RET fusion (or rearrangement) positive tumors; **AND**
 - D. Individual is radioactive iodine-refractory, or ineligible for radioactive iodine.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 22, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 2, 2024.
 - a. Non-Small Cell Lung Cancer. V7.2024. Revised June 26, 2024.
 - b. Thyroid Carcinoma. V3.2024. Revised June 18, 2024.
 - c. Biliary Tract Cancers.V2.2024. Revised April 19, 2024.

6. NCT03037385. ClinicalTrials.gov. U.S. National Library of Medicine. Available at <https://clinicaltrials.gov/ct2/show/NCT03037385?term=nct03037385&draw=2&rank=1>.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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