# Gavreto® (pralsetinib)
## (Oral)

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## I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

## II. Dosing Limits

**A. Quantity Limit (max daily dose) [NDC Unit]:**

- Gavreto 100 mg capsules: 4 capsules per day

**B. Max Units (per dose and over time) [HCPCS Unit]:**

- 400 mg per day

## III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**

Universal Criteria [1]

- Patient has RET fusion positive disease as detected by an FDA-approved or CLIA compliant test❖; **AND**
- Used as a single agent; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- Patient must not have had major surgery within the preceding 14 days or have a surgical wound that has not fully healed; **AND**
- Therapy will not be used concomitantly with other RET-type targeted therapies (e.g., selpercatinib, cabozantinib, vandetanib, etc.); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong or moderate CYP3A inhibitors and/or P-gp inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, voriconazole, verapamil, fluconazole, cyclosporine, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong or moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, bosentan, efavirenz, phenobarbital, etc.), or if therapy

is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

**Non-Small Cell Lung Cancer (NSCLC) † ‡ Φ [1-3]**

- Patient has recurrent, advanced, or metastatic disease *(excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease)* or mediastinal lymph node recurrence with prior radiation therapy

**Thyroid Cancer † ‡ Φ [1,2,6]**

- Patient has follicular, oncocytic, or papillary carcinoma; **AND**
  - Patient is at least 12 years of age; **AND**
  - Patient has metastatic, advanced, OR unresectable locoregional recurrent or persistent disease; **AND**
  - Patient has progressive and/or symptomatic disease that is not amenable to radioactive iodine (RAI) therapy; **OR**
- Patient has anaplastic carcinoma; **AND**
  - Used as neoadjuvant therapy for borderline resectable locoregional disease; **OR**
  - Used as first- or second-line therapy for metastatic disease

**Biliary Tract Cancers – Gallbladder Cancer ‡ [2,7]**

- Used as neoadjuvant therapy for resectable locoregionally advanced disease; **AND**
  - Patient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; **OR**
  - Patient has incidental finding on pathologic review (cystic duct node positive); **OR**
  - Patient has mass on imaging

❖ *If confirmed using an immunotherapy assay-http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

## IV. Renewal Criteria [1]

Coverage may be renewed based on the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe or life-threatening interstitial lung disease or pneumonitis, severe hypertension,

severe hepatotoxicity, severe or life-threatening hemorrhage, tumor lysis syndrome, impaired wound healing, etc.

## V. Dosage/Administration [1]

| Indication | Dose |
|---|---|
| All Indications | The recommended dosage is 400 mg orally once daily until disease progression or unacceptable toxicity. |

## VI. Billing Code/Availability Information

HCPCS Code(s):

- J8999: Prescription drug, oral, chemotherapeutic, nos
- C9399: Unclassified drugs or biologicals *(for hospital outpatient use ONLY)*

NDC:

- Gavreto 100 mg capsules: 50242-0210-xx

## VII. References


1. Gavreto [package insert]. South San Francisco, CA; Genentech, Inc., March 2024. Accessed May 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for pralsetinib. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2024.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer Version 5.2024. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed May 2024.
4. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Date: 1/31/17. Identifier NCT03037385: Phase 1/2 Study of the Highly-selective RET Inhibitor, Pralsetinib (BLU-667), in Patients With Thyroid Cancer, Non-Small Cell Lung Cancer, and Other Advanced Solid Tumors (ARROW); [Accessed 9/10/20]; Available from: https://clinicaltrials.gov/ct2/show/NCT03037385?term=NCT03037385&draw=2&rank=1.
5. Paik PK, Felip E, Veillon R, et al. Tepotinib in non-small cell lung cancer with MET exon 14 skipping mutations [published online May 29, 2020]. *The New England Journal of Medicine*. doi: 10.1056/NEJMoa2004407.
6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Thyroid Carcinoma Version 2.2024. National Comprehensive

Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed May 2024.

7. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Biliary Tract Cancers Version 2.2024. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed April 2024.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---|---|
| C23 | Malignant neoplasm of gallbladder |
| C24.8 | Malignant neoplasm of overlapping sites of biliary tract |
| C24.9 | Malignant neoplasm of biliary tract, unspecified |
| C33 | Malignant neoplasm of trachea |
| C34.00 | Malignant neoplasm of unspecified main bronchus |
| C34.01 | Malignant neoplasm of right main bronchus |
| C34.02 | Malignant neoplasm of left main bronchus |
| C34.10 | Malignant neoplasm of upper lobe, unspecified bronchus or lung |
| C34.11 | Malignant neoplasm of upper lobe, right bronchus or lung |
| C34.12 | Malignant neoplasm of upper lobe, left bronchus or lung |
| C34.2 | Malignant neoplasm of middle lobe, bronchus or lung |
| C34.30 | Malignant neoplasm of lower lobe, unspecified bronchus or lung |
| C34.31 | Malignant neoplasm of lower lobe, right bronchus or lung |
| C34.32 | Malignant neoplasm of lower lobe, left bronchus or lung |
| C34.80 | Malignant neoplasm of overlapping sites of unspecified bronchus or lung |
| C34.81 | Malignant neoplasm of overlapping sites of right bronchus and lung |
| C34.82 | Malignant neoplasm of overlapping sites of left bronchus and lung |
| C34.90 | Malignant neoplasm of unspecified part of unspecified bronchus or lung |
| C34.91 | Malignant neoplasm of unspecified part of right bronchus or lung |
| C34.92 | Malignant neoplasm of unspecified part of left bronchus or lung |
| C73 | Malignant neoplasm of thyroid gland |
| Z85.118 | Personal history of other malignant neoplasm of bronchus and lung |
| Z85.850 | Personal history of malignant neoplasm of thyroid |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |