Pharmacy Policy Bulletin: J-0279 RET Kinase Inhibitors - Commercial and Healthcare Reform	
Number: J-0279	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0279-009	**Original Date:** 06/03/2020
Effective Date: 10/28/2024	**Review Date:** 10/02/2024

Drugs Product(s):	• Gavreto (pralsetinib) • Retevmo (selpercatinib)

FDA-Approved Indication(s):	• Gavreto
	  ○ 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.
	  ○ 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).
	• Retevmo
	  ○ Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a *RET* gene fusion, as detected by an FDA-approved test.
	  ○ Treatment of adult and pediatric patients 2 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a *RET* mutation, as detected by an FDA-approved test, who require systemic therapy.
	  ○ Treatment of adult and pediatric patients 2 years of age and older with advanced or metastatic thyroid cancer with a *RET* gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
	  ○ Treatment of adult and pediatric patients 2 years of age and older with locally advanced or metastatic solid tumors with a *RET* gene fusion, as detected by an FDA approved test, that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.

Background:	• When *RET* is classified as mutant or fused, it acts as an oncogenic driver and promotes cell proliferation of tumor cell lines. Retevmo and Gavreto inhibit wild-

	type *RET* and fusion-positive *RET* in tumor cells to decrease tumor cell growth and result in tumor cell death. • FDA-approved companion diagnostic tests for Gavreto include for NSCLC the Oncomine Dx Target Test. FDA approved companion diagnostic tests for Retevmo include the Oncomine Dx Target Test for NSCLC, MTC, and TC and the FoundationOne CDx for solid tumors. For additional information regarding FDA-approved companion diagnostics, please visit: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools • Gavreto should be taken once daily on an empty stomach (no food intake for at least 2 hours before and 1 hour after taking the medications. • Retevmo may be taken with or without food unless co-administered with a proton pump inhibitor (PPI). Avoid concomitant use of a PPI, a histamine-2 (H2) receptor antagonist, or a locally-acting antacid with Retevmo. • ICD-10-Code Information: o ICD-10: C80 “Malignant neoplasm without specification of site” and multiple other ICD-codes may apply to a diagnosis of solid tumors for Retevmo. • Prescribing Considerations: o Kinase inhibitors should be prescribed under the supervision of a hematologist/oncologist.

Approval Criteria

I. Initial Authorization

A. Gavreto

1. NSCLC

When a benefit, coverage of Gavreto may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of NSCLC (ICD-10: C34).
c. Disease is classified as metastatic.
d. Disease is classified as *RET* fusion-positive as detected by an FDA approved test.

2. Thyroid Cancer

When a benefit, coverage of Gavreto may be approved when all of the following criteria are met **(a. through e.)**:

a. The member is 12 years of age or older.
b. The member has a diagnosis of thyroid cancer (ICD-10 C73).
c. Disease is classified as advanced or metastatic.
d. Disease is classified as *RET* fusion-positive.
e. If radioactive iodine is appropriate for the member, the member is radioactive iodine-refractory.

B. Retevmo

1. NSCLC

When a benefit, coverage of Retevmo may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of NSCLC (ICD-10: C34).
c. Disease is locally advanced or metastatic.
d. Disease harbors a *RET* gene fusion as detected by an FDA approved test.

2. Thyroid Cancer

When a benefit, coverage of Retevmo may be approved when all of the following criteria are met **(a. and b.)**:

a. The member is 2 years of age or older.

b. The member meets one (1) of the following criteria **(i. or ii.)**:

i. The member has a diagnosis of thyroid cancer (ICD-10: C73), classified as medullary thyroid cancer and meets all of the following criteria **(A) and B))**:

A) Disease is classified as advanced or metastatic.

B) Disease harbors a *RET* mutation as detected by an FDA approved test.

ii. The member has a diagnosis of thyroid cancer (ICD-10: C73) and meets all of the following criteria **(A), B), and C))**:

A) Disease is classified as advanced or metastatic.

B) Disease harbors a *RET* gene fusion as detected by an FDA approved test.

C) If radioactive iodine is appropriate for the member, the member is radioactive iodine-refractory.

3. Solid Tumors

When a benefit, coverage of Retevmo may be approved when all of the following criteria are met **(a. through d.)**

a. The member is 2 years of age or older.

b. The member has a diagnosis of locally advanced or metastatic solid tumor(s) (No ICD-10 Code).

c. Disease harbors a *RET* gene fusion as detected by an FDA approved test.

d. The member meets one (1) of the following criteria **(i. or ii.):**

i. The member has no satisfactory alternative treatments.

ii. The member's tumor(s) have progressed on or following prior systemic treatment.

II. Reauthorization

When a benefit, reauthorization of Gavreto or Retevmo may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member is tolerating therapy and has experienced a therapeutic response defined as one (1) of the following **(1. or 2.)**:

1. Disease improvement

2. Delayed disease progression

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

IV. Coverage of oncology medications listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

None

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Gavreto [package insert].South San Fransisco, CA: Blueprint Medicines Corporation; March 2024 .
2. Retevmo [package insert]. Indianapolis, Indiana: Eli Lilly and Company; June 2024.
3. U.S Food & Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools. Accessed August 12, 2024.