MEDICATION POLICY:

RET Kinase Inhibitor

Generic Name: Pralsetinib; Selpercatinib

Therapeutic Class or Brand Name: Gavreto®, Retevmo®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/15/2020

Date Last Reviewed / Revised: 2/24/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met.)

I. Documentation of one of the following diagnoses A through C AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Non-small cell lung cancer (NSCLC)

i. Documentation of locally advanced or metastatic NSCLC.

ii. Documentation of rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test.

iii. Gavreto or Retevmo will be used as a single agent.

iv. Minimum age requirement: ≥18 years old.

B. Thyroid cancer

i. Documentation of advanced or metastatic disease.

ii. Documentation that systemic therapy is required and meets one of the following criteria, 1 or 2:

1. Documentation of medullary thyroid cancer (MTC)

a. Documentation of RET mutation, as detected by an FDA-approved test.

b. Request is for Retevmo.

c. Retevmo will be used as a single agent.

d. Minimum age requirement: ≥ 2 years old.

2. Thyroid cancer

a. Documentation of RET gene fusion, as detected by an FDA-approved test.

b. Documentation of radioactive iodine-refractory disease (if radioactive iodine is appropriate).

c. Gavreto or Retevmo will be used as a single agent.

d. Minimum age requirement: Retevmo ≥ 2 years old; Gavreto ≥ 12 years old

C. Solid tumor

i. Documentation of locally advanced or metastatic solid tumor.

ii. Documentation of RET gene fusion, as detected by an FDA-approved test.

iii. Request is for Retevmo.

iv. Documentation of progression on or following prior systemic treatment or have no satisfactory alternative treatment options.

v. Retevmo will be used as a single agent.

vi. Minimum age requirement: ≥ 2 years old.

II. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity is limited to a 30-day supply.
- Gavreto
  - 100 mg capsule: 400 mg once daily
- Retevmo
  - Tablets: 40 mg, 80 mg, 120 mg, 160 mg
    - Adults and adolescents ≥12 years old
      - Less than 50 kg: 120mg twice daily
      - 50 kg or greater: 160mg twice daily
    - Pediatric patients 2 years old to < 12 years old
      - <0.33m^2: not recommended

- 0.33 m^2 to 0.65 m^2: 40 mg three times daily
- 0.66 m^2 to 1.08 m^2: 80 mg twice daily
- 1.09 m^2 to 1.52 m^2: 120 mg twice daily
- ≥1.53 m^2: 160 mg twice daily

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

- N/A

REFERENCES

1. Gavreto (Pralsetinib). Prescribing Information. South San Francisco, CA; Genetech. March 2024. Accessed January 24, 2025. www.accessdata.fda.gov/drugsatfda_docs/label/2024/213721s015lbl.pdf
2. Retevmo (Selpercatinib). Prescribing Information. Indianapolis, IN; Lilly. December 2024. Accessed January 24, 2025. www.accessdata.fda.gov/drugsatfda_docs/label/2024/213246s014lbl.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. Version 5.2024. Updated January 15, 2025. Accessed January 24, 2025. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 3.2025. Updated January 14, 2025. Accessed January 24, 2025. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf