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: 2/16/2023

PRIOR AUTHORIZATION CRITERIA

(MAY BE CONSIDERED MEDICALLY NECESSARY WHEN CRITERIA I - VI ARE MET)

I. Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion as detected by an FDA approved test.

II. Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy.

III. Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer (MTC) who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

IV. Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.

   A. Request is for Retevmo®

V. Prescribed by or in consultation with an oncologist or hematologist specialist.

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

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- Interstitial Lung Disease (ILD)/Pneumonitis: Withhold GAVRETO® for Grade 1 or 2 reactions until resolution and then resume at a reduced dose. Permanently discontinue for recurrent ILD/pneumonitis. Permanently discontinue for Grade 3 or 4 reactions.
- Hypertension: Do not initiate GAVRETO® or REVTEMO® in patients with uncontrolled hypertension. Optimize blood pressure (BP) prior to initiating GAVRETO® or REVTEMO®. Monitor BP after 1 week, at least monthly thereafter and as clinically indicated. Withhold, reduce dose, or permanently discontinue based on severity.

- Hepatotoxicity: Monitor ALT and AST prior to initiating GAVRETO® or REVTEMO®, every 2 weeks during the first 3 months, then monthly thereafter and as clinically indicated. Withhold, reduce dose, or permanently discontinue based on severity.
- QT Interval Prolongation: Monitor patients who are at significant risk of developing QTc prolongation with RETEVMO®. Assess QT interval, electrolytes and TSH at baseline and periodically during treatment. Monitor QT interval more frequently when RETEVMO® is concomitantly administered with strong and moderate CYP3A inhibitors or drugs known to prolong QTc interval. Withhold and dose reduce or permanently discontinue RETEVMO based on severity.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Gavreto®
  - 100 mg capsule: 4 capsules Daily per 30-day supply
- Retevmo®
  - 40 mg, 80 mg capsules:
    - Less than 50 kg: 120mg twice daily per 30-day supply
    - 50 kg or greater: 160mg twice daily per 30-day supply

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

- N/A

REFERENCES

1. Gavreto® (Pralsetinib). Prescribing Information. South San Francisco, CA; Genetech. September 2022. Accessed February 16, 2023. https://www.gene.com/download/pdf/gavreto_prescribing.pdf.
2. Retevmo® (Selpercatinib). Prescribing Information. Indianapolis, IN; Lilly. September 2022. Accessed February 16, 2023. https://uspl.lilly.com/retevmo/retevmo.html#pi.
3. NCCN Guidelines. Thyroid Carcinoma (Version 3.2022). https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. February 16, 2023.
4. NCCN Guidelines. Non-Small Cell Lung Cancer (Version 1.2023). https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. February 16, 2023.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.