MEDICATION POLICY:

RET Kinase Inhibitor

Generic Name: Pralsetinib; Selpercatinib

Therapeutic Class or Brand Name: Gavreto®, Retevmo®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 215340760001; 215340790001

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/15/2020

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

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

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

II. 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.

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

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

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 severit

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Gavreto®
  - 100 mg capsule: 4 capsules Daily per 30 day supply
- Retevmo®
  - 40 mg, 80 mg capsules: 120mg – 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) [package insert]. Cambridge, MA: Blueprint Medicines Corporation, December 2020. Available at: https://www.blueprintmedicines.com/uspi/GAVRETO.pdf .
2. Retevmo® (Selpercatinib) [package insert]. Indianapolis, IN: Lilly USA, LLC, May 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213246s000lbl.pdf.
3. Medispan.
4. NCCN Guidelines Version 3.2020 – Thyroid Carcinoma https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf
5. NCCN Guidelines Version 2.2021 – Non Small Cell Lung Cancer https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf