BlueCross BlueShield Federal Employee Program

GAVRETO
(pralsetinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Gavreto (pralsetinib) is a kinase inhibitor of wild-type *RET* and oncogenic *RET* fusions and mutations. Certain *RET* fusion proteins and activating point mutations can drive tumorigenic potential through hyperactivation of downstream signaling pathways leading to uncontrolled cell proliferation. Gavreto exhibits anti-tumor activity in models harboring oncogenic *RET* fusions or mutations (1).

Regulatory Status

FDA-approved indications: Gavreto is a kinase inhibitor indicated for the treatment of: (1)

- Adult patients with metastatic rearranged during transfection (*RET*) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test
- 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 refractory iodine is appropriate)

Patients should be selected for treatment with Gavreto based on the presence of a *RET* gene fusion (NSCLC or thyroid cancer) (1).

Gavreto has warnings regarding hepatotoxicity and hypertension. AST and ALT should be monitored prior to initiating Gavreto, every 2 weeks during the first 3 months, then monthly thereafter and as clinically indicated. Gavreto should not be initiated in patients with uncontrolled hypertension and blood pressure should be optimized prior to initiation. Blood pressure should be monitored after 1 week, at least monthly thereafter and as clinically indicated (1).

Gavreto can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective non-hormonal contraception during treatment with Gavreto and for 2 weeks after the final dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Gavreto and for 1 week after the final dose (1).

The safety and effectiveness of Gavreto have not been established in pediatric patients less than

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18 years of age with *RET* fusion-positive NSCLC or in pediatric patients less than 12 years of age with *RET* fusion-positive thyroid cancer (1).

Summary

Gavreto (pralsetinib) is a kinase inhibitor of wild-type *RET* and oncogenic *RET* fusions and mutations. Certain *RET* fusion proteins and activating point mutations can drive tumorigenic potential through hyperactivation of downstream signaling pathways leading to uncontrolled cell proliferation. Gavreto exhibits anti-tumor activity in models harboring oncogenic *RET* fusions or mutations (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Gavreto while maintaining optimal therapeutic outcomes.

References

1. Gavreto [package insert]. South San Fracisco, CA: Rigel Pharmaceuticals, Inc.; June 2024.
2. NCCN Drugs & Biologics Compendium® Pralsetinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.