

SPECIALTY GUIDELINE MANAGEMENT

GAVRETO (pralsetinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Gavreto is indicated for the 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.
2. Gavreto is indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC) who require systemic therapy.
3. Gavreto is indicated for the 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).

B. Compendial Uses

Recurrent, advanced, or metastatic NSCLC with *RET* rearrangement-positive tumors

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Documentation of the presence of a rearranged during transfection (*RET*) gene fusion (NSCLC or thyroid cancer) or a specific *RET* gene mutation (MTC) in tumor specimens or plasma.

III. CRITERIA FOR INITIAL APPROVAL

A. **Non-Small Cell Lung Cancer**

Authorization of 12 months may be granted as a single agent for treatment of recurrent, advanced, or metastatic non-small cell lung cancer when the tumors have a *RET* gene fusion.

B. **Medullary Thyroid Cancer**

Authorization of 12 months may be granted for treatment of members 12 years of age and older with advanced or metastatic medullary thyroid cancer with a *RET* gene mutation.

C. **Thyroid Cancer**

Authorization of 12 months may be granted for treatment of members 12 years of age and older with advanced or metastatic radioactive iodine-refractory (if radioactive iodine is appropriate) thyroid cancer whose tumors have a *RET* gene fusion.

Reference number(s)
4206-A

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Gavreto [package insert]. Cambridge, MA: Blueprint Medicines Corporation; December 2020.
2. The NCCN Drugs & Biologics Compendium 2021 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed July 2, 2021.