Reference number(s)
4206-A

Specialty Guideline Management
Gavreto

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Gavreto	pralsetinib

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.

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.
- 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).

Compendial Uses[2]

- NSCLC with RET rearrangement-positive tumors
- Anaplastic thyroid cancer
- Follicular, oncocytic, papillary thyroid cancer
- Gallbladder cancer

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

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 in tumor specimens or plasma.

Coverage Criteria

Non-Small Cell Lung Cancer[1,2]

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 and the member has not experienced disease progression on therapy with a RET rearrangement positive-targeted regimen.

Anaplastic Thyroid Cancer[2]

Authorization of 12 months may be granted for treatment of stage IV anaplastic thyroid cancer with a RET gene fusion when used as a single agent.

Thyroid Cancer[1,2]

Authorization of 12 months may be granted for treatment of progressive/symptomatic, advanced, or metastatic thyroid cancer with a RET gene fusion when any of the following criteria are met:

- Member has follicular or papillary thyroid carcinoma and disease is not amenable to radioactive iodine therapy (RAI).
- Member has oncocytic thyroid carcinoma.

Gallbladder Cancer[2]

Authorization of 12 months may be granted for neoadjuvant treatment of resectable locoregionally advanced gallbladder cancer with a RET gene fusion when used as a single agent.

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Continuation of Therapy

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

References

1. Gavreto [package insert]. South San Francisco, CA: Rigel Pharmaceuticals, Inc.; June 2024.
2. The NCCN Drugs & Biologics Compendium® 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed July 9, 2025.

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