PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Gavreto Prior Authorization Policy
- Gavreto® (pralsetinib capsules – Blueprint Medicines)

REVIEW DATE: 09/18/2024

OVERVIEW

Gavreto, a kinase inhibitor, is indicated for the following uses:[1]

- **Non-small cell lung cancer**, with metastatic *RET* fusion-positive disease in adults, as detected by an FDA approved test.
- **Thyroid cancer**, with advanced or metastatic *RET* fusion-positive disease in adults and pediatric patients ≥ 12 years of age who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
  This thyroid cancer indication was approved under accelerated approval based on overall response rate and duration of response. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Guidelines

Gavreto is addressed in the National Comprehensive Cancer Network (NCCN) guidelines:

- **Non-Small Cell Lung Cancer:** Guidelines (version 9.2024 – September 9, 2024) recommend Gavreto and Retevmo® (selpercatinib capsules) as "preferred" first-line therapies for *RET* rearrangement-positive recurrent, advanced, or metastatic disease (both category 2A).[2] For patients who were started on other systemic therapy options and had disease progression, Gavreto and Retevmo are recommended as "preferred" subsequent therapies (category 2A). The NCCN compendium recommend Gavreto for locoregional recurrence or symptomatic local disease with *RET* rearrangement with no evidence of disseminated disease (both category 2B).[4]
- **Thyroid Carcinoma:** Guidelines (version 4.2024 – August 19, 2024) recommend the use of Gavreto and Retevmo in a variety of therapy settings.[3] The guidelines recommend Gavreto and Retevmo for differentiated thyroid carcinoma (papillary, follicular, oncocytic carcinoma) with *RET* fusion-positive tumors for unresectable locoregional recurrent or persistent disease, or distant metastatic disease that is not amenable to radioactive therapy as "useful in certain circumstances" (category 2A). For recurrent, persistent, locoregional or metastatic medullary thyroid cancer, Gavreto (category 2B) or Retevmo (category 2A) are listed as "preferred" options for positive *RET* pathogenic variant. For anaplastic carcinoma, Gavreto or Retevmo can be used for *RET*-fusion positive tumors as neoadjuvant therapy for locoregional disease (category 2A). For metastatic anaplastic carcinoma, molecular testing for actionable mutations is recommended; if positive for *RET* fusion, Gavreto or Retevmo can be considered (category 2A).[3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Gavreto. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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Coverage of Gavreto is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Differentiated Thyroid Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C and D):
   Note: Differentiated thyroid cancer includes papillary, follicular, and oncocytic thyroid cancer; see below for other types of thyroid cancer.
   A) Patient is ≥ 12 years of age; AND
   B) Patient has unresectable, recurrent, or metastatic disease; AND
   C) Patient has rearranged during transfection (*RET*) fusion-positive or *RET*-mutation-positive disease; AND
   D) Patient meets both of the following (i and ii):
      i. The disease requires treatment with systemic therapy; AND
      ii. The disease is radioactive iodine-refractory.

2. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has recurrent, advanced, or metastatic disease; AND
   C) Patient has rearranged during transfection (*RET*) fusion-positive disease as detected by an approved test.

Other Uses with Supportive Evidence

3. **Anaplastic Thyroid Cancer**. Approve for 1 year if the patient meets ALL of the following (A, B and C):
   A) Patient is ≥ 12 years of age; AND
   B) Patient has unresectable, recurrent, or metastatic disease; AND
   C) Patient has rearranged during transfection (*RET*) fusion-positive or *RET*-mutation-positive disease.

4. **Medullary Thyroid Cancer**. Approve for 1 year if the patient meets ALL of the following (A, B, C and D):
   A) Patient is ≥ 12 years of age; AND
   B) Patient has unresectable, recurrent, or metastatic disease; AND
   C) The disease is positive for rearranged during transfection (*RET*) pathogenic variant; AND
   D) Patient is continuing therapy with Gavreto.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Gavreto is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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REFERENCES

1. Gavreto® capsules [prescribing information]. Cambridge, MA: Blueprint Medicines; March 2024.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 9.2024– September 9, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 16, 2024.
3. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 4.2024 – August 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 16, 2024.
4. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 15, 2024. Search term: pralsetinib.

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