PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 10/12/2022

OVERVIEW

Gavreto, a kinase inhibitor, is indicated for the treatment of the following conditions:[1]

- **Medullary thyroid cancer**, in adults and pediatric patients ≥ 12 years of age with advanced or metastatic rearranged during transfection (*RET*)-mutant disease who require systemic therapy.
- **Non-small cell lung cancer**, in adults with metastatic *RET* fusion-positive disease as detected by an FDA approved test.
- **Thyroid cancer**, in adults and pediatric patients ≥ 12 years of age with advanced or metastatic *RET* fusion-positive disease who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

All of the above indications are 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 5.2022 – September 26, 2022) 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).
- **Thyroid Carcinoma:** Guidelines (version 2.2022 – May 5, 2022) 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, or Hürthle cell carcinoma) with *RET* fusion-positive tumors for locally recurrent, advanced, and/or metastatic disease that is not amenable to radioactive therapy (category 2A). For recurrent, persistent, locoregional or metastatic medullary thyroid cancer, Gavreto or Retevmo are listed as preferred options for *RET* mutation-positive disease (category 2A). 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

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

FDA-Approved Indications

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

2. **Thyroid Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 12 years of age; AND
   - **B)** Patient has rearranged during transfection (*RET*) fusion-positive or *RET*-mutation-positive disease; AND
   - **C)** Patient meets ONE of the following criteria (i or ii):
     - **i.** Patient has anaplastic thyroid cancer; OR
     - **ii.** The disease requires treatment with systemic therapy and patient meets ONE of the following criteria (a or b):
       - **a)** The patient has medullary thyroid cancer; OR
       - **b)** The disease is radioactive iodine-refractory.

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.

REFERENCES

1. Gavreto® capsules [prescribing information]. Cambridge, MA: Blueprint Medicines; April 2021.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2022– September 26, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed October 4, 2022.
3. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 5, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 4, 2022.