VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/09/2020; selected revision 12/09/2020

OVERVIEW

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

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

  All of the above indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Guidelines

The National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 8.2020 – September 15, 2020) recommend Gavreto and Retevmo™ (selpercatinib capsules) as "preferred" (both category 2A) first-line therapies for RET rearrangement-positive disease.[2] For patients who were started on other systemic therapy options and had disease progression, Gavreto and Retevmo are recommended as "preferred" subsequent therapies.

Gavreto is not addressed in the thyroid guidelines. In the NCCN thyroid carcinoma guidelines (version 2.2020 – July 15, 2020) the use of Retevmo™ (selpercatinib capsules) is addressed in a variety of therapy settings.[3] Retevmo is a category 2A recommended therapy for patients with *RET* fusion-positive thyroid tumors that are radioactive iodine refractory. For recurrent, persistent, or metastatic medullary thyroid cancer, Caprelsa or Cometriq are both category 1 "preferred" options. Retevmo is listed as a category 2A "preferred" regimen for *RET* mutation-positive medullary thyroid cancer. For anaplastic carcinoma, molecular testing for actionable mutations is recommended; if positive for *RET* fusion, Retevmo can be considered (category 2A).

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 the following criteria:

FDA-Approved Indications

1. **Medullary Thyroid Cancer.** Approve for 3 years if the patient meets the following criteria (A, B, and C):
   Note: For other types of thyroid cancer see criteria below for "Thyroid Cancer".
   A) Patient is ≥ 12 years of age; AND
   B) Patient has advanced or metastatic rearranged during transfection (*RET*)-mutant disease; AND
   C) The disease requires treatment with systemic therapy.

2. **Non-Small Cell Lung Cancer.** Approve for 3 years 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.

3. **Thyroid Cancer.** Approve for 3 years if the patient meets the following criteria (A, B, C, and D):
   Note: For "Medullary Thyroid Cancer" see above criteria.
   A) Patient is ≥ 12 years of age; AND
   B) Patient has advanced or metastatic rearranged during transfection (RET) fusion-positive disease; AND
   C) The disease is radioactive iodine-refractory; AND
   D) The disease requires treatment with systemic therapy.

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 Corporation; December, 2020.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 8.2020 – September 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed September 18, 2020.
3. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2020 – July 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on December 7, 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/09/2020
Selected Revision	**Non-Small Cell Lung Cancer:** Changed approval duration to 3 years from 1 year. Deleted "FDA-approved" in reference to testing and also deleted criteria requiring specialist physician, to be in-line with other oral oncology policies.	09/23/2020
Selected Revision	**Medullary Thyroid Cancer:** Added new approval condition and criteria based on FDA-approved indication. **Thyroid Cancer:** Added new approval condition and criteria based on FDA-approval.	12/09/2020