VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Retevmo Prior Authorization Policy
- Retevmo® (selpercatinib capsules and tablets– Eli Lilly)

REVIEW DATE: 06/05/2024

OVERVIEW

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

- **Non-small cell lung cancer**, locally advanced or metastatic with a rearranged during transfection (*RET*) gene fusion, as detected by an FDA-approved test in adults.
- **Solid tumors,** locally advanced or metastatic solid tumors with a *RET* gene fusion in patients ≥ 2 years of age who have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.
- **Thyroid cancer**, advanced or metastatic *RET*-mutant medullary, in patients ≥ 2 years of age who require systemic therapy as detected by an FDA-approved test.
- **Thyroid cancer**, advanced or metastatic *RET* gene fusion-positive, in patients ≥ 2 years of age who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate), as detected by an FDA-approved test.

The indications of *RET* gene fusion solid tumors and *RET* mutant medullary thyroid cancers above were accelerated approvals based on overall response rate and duration of response. Continued approval of these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Guidelines

Retevmo is addressed in the National Comprehensive Cancer Network (NCCN) compendium for a variety of solid tumors.[2] Retevmo is addressed in NCCN guidelines:

- **Histiocytic Neoplasms:** NCCN guidelines (version 1.2024 – March 15, 2024) recommend Retevmo as an agent that may be "useful in certain circumstances" as the first- or subsequent-line treatment for the following types of histiocytic neoplasm with *RET* fusion: Langerhans cell histiocytosis, Erdheim-Chester disease, and Rosai-Dorfman disease (category 2A).[3]
- **Non-Small Cell Lung Cancer:** NCCN guidelines (version 5.2024 – April 23, 2024) recommend Retevmo as a "preferred" option for first-line and subsequent treatment of patients with *RET* rearrangement-positive recurrent, advanced, or metastatic non-small cell lung cancer (category 2A).[2,4]
- **Thyroid Carcinoma:** NCCN guidelines (version 2.2024 – March 12, 2024) recommend Retevmo and Gavreto® (pralsetinib capsules) as "preferred regimens" for the treatment of *RET* pathogenic variant recurrent or persistent locoregional or metastatic medullary carcinoma (category 1).[5] Retevmo is also recommended for the treatment of locally recurrent, advanced, and/or metastatic *RET*-gene fusion positive thyroid carcinoma that is not amenable to radioactive iodine therapy as "useful in certain circumstances" (category 2A). Additionally NCCN recommends Retevmo for *RET*-fusion positive anaplastic thyroid carcinoma for locoregional disease and metastatic disease (category 2A).[5]

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Retevmo 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 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)** The tumor is rearranged during transfection (*RET)* fusion-positive.

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

3. **Solid Tumors.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   Note: Examples of solid tumors include breast cancer, cervical cancer, cholangiocarcinoma, colorectal cancer, esophageal cancer, gastric cancer, ovarian cancer, pancreatic adenocarcinoma, salivary gland tumors, soft tissue sarcoma, small bowel adenocarcinoma, and unknown primary cancer.
   - **A)** Patient is ≥ 2 years of age; AND
   - **B)** Patient has recurrent, advanced, or metastatic disease; AND
   - **C)** The tumor is rearranged during transfection (*RET)* fusion-positive.

Other Uses with Supportive Evidence

4. **Histiocytic Neoplasm.** 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 meets ONE of the following (i, ii, or iii):
     - **i.** Patient has Langerhans cell histiocytosis; OR
     - **ii.** Patient has Erdheim-Chester disease; OR
     - **iii.** Patient has Rosai-Dorfman disease; AND
   - **C)** Patient has a rearranged during transfection (*RET)* fusion.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Retevmo 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. Retevmo® tablets and capsules [prescribing information]. Indianapolis, IN: Eli Lilly and Company; May 2024.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 31, 2024. Search term: selpercatinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – March 15, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 3, 2024.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2024 – April 23, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 3, 2024.
5. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2024 – March 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 3, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/14/2023
Annual Revision	A new formulation of Retevmo tablets was added to the policy. The same criteria apply as those for the Retevmo capsules. **Thyroid Cancer:** Age requirement was changed from ≥ 12 years of age to ≥ 2 years of age due to expanded FDA labeled indication in pediatrics. The term "*RET* pathogenic variant" was added to criterion, "patient has rearranged during transfection (*RET)* fusion-positive, *RET* mutation-positive disease, or *RET* pathogenic variant." **Solid Tumors:** Age requirement was changed from ≥ 18 years of age to ≥ 2 years of age due to expanded FDA labeled indication in pediatrics.	06/05/2024
Update	The overview section was updated from accelerated approval language to full approval for the indication of advanced or metastatic RET fusion-positive thyroid cancer in adults and pediatric patients ≥ 2 years of age who are radioactive iodine-refractory, and require systemic therapy.	06/13/2024