PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/01/2022; selected revision 06/22/2022, 09/28/2022, and 10/12/2022

OVERVIEW

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

- **Non-small cell lung cancer**, locally advanced or metastatic rearranged during transfection (*RET*) fusion-positive in adults.
- **Solid tumors,** locally advanced or metastatic solid tumors with a *RET* gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options, in adults.
- **Thyroid cancer**, advanced or metastatic *RET*-mutant medullary, in patients ≥ 12 years of age who require systemic therapy.
- **Thyroid cancer**, advanced or metastatic *RET* fusion-positive, in patients ≥ 12 years of age who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

All of these indications were accelerated approvals based on overall response rate and duration of response. Continued approval of the indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Guidelines

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

- **Histiocytic Neoplasms:** Guidelines (version 1.2022 – May 20, 2022) recommend Retevmo as an agent that may be useful 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:** Guidelines (version 3.2022 – March 16, 2022) 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:** Guidelines (version 2.2022 – May 5, 2022) recommend Retevmo and Gavreto® (pralsetinib capsules) as preferred regimens for the treatment of *RET* mutation-positive recurrent or persistent locoregional or metastatic medullary carcinoma.[5] Retevmo is also recommended for the treatment of locally recurrent, advanced, and/or metastatic *RET*-fusion positive thyroid carcinoma that is not amenable to radioactive iodine therapy (category 2A). Additionally NCCN recommends Retevmo for *RET*-fusion positive anaplastic thyroid carcinoma (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 the following criteria (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 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.

3. **Solid Tumors.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   Note: Examples of solid tumors include pancreatic adenocarcinoma, colorectal cancer, breast cancer, and ovarian cancer.
   - **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.

Other Uses with Supportive Evidence

4. **Histiocytic Neoplasm.** 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 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® capsules [prescribing information]. Indianapolis, IN: Eli Lilly and Company; September 2022.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 26, 2022. Search term: selpercatinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 27, 2022.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2022 – March 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 27, 2022.
5. 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 May 27, 2022.