

Commercial/Healthcare Exchange PA Criteria

Effective: July 8, 2020

Prior Authorization: Retevmo

Products Affected: Retevmo (selpercatinib) oral capsules

Medication Description:

Retevmo (selpercatinib) is a kinase inhibitor. Selpercatinib inhibited wild-type RET and multiple mutated RET isoforms as well as VEGFR1 and VEGFR3 with IC50 values ranging from 0.92 nM to 67.8 nM. In other enzyme assays, selpercatinib also inhibited FGFR 1, 2, and 3 at higher concentrations that were still clinically achievable. In cellular assays, selpercatinib inhibited RET at approximately 60-fold lower concentrations than FGFR1 and 2 and approximately 8-fold lower concentration than VEGFR3.

Certain point mutations in RET or chromosomal rearrangements involving in-frame fusions of RET with various partners can result in constitutively activated chimeric RET fusion proteins that can act as oncogenic drivers by promoting cell proliferation of tumor cell lines. In in vitro and in vivo tumor models, selpercatinib demonstrated anti-tumor activity in cells harboring constitutive activation of RET protein resulting from gene fusions and mutations, including CCDC6-RET, KIF5B-RET, RET V804M, and RET M918T. In addition, selpercatinib showed anti-tumor activity in mice intracranially implanted with a patient-derived RET fusion positive tumor.

Covered Uses:

1. Adult patients with metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC);
2. Adult and pediatric patients ≥ 12 years of age with advanced or metastatic *RET*-mutant medullary thyroid cancer who require systemic therapy;
3. Adult and pediatric patients ≥ 12 years of age with advanced or metastatic *RET* fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. RET mutation status
3. Previous therapies tried and failed

Age Restrictions:

1. Non-Small Cell Lung Cancer (NSCLC): 18 years of age and older
2. Medullary Thyroid Cancer: 12 years of age and older
3. Thyroid Cancer: 12 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration: 3 years

Other Criteria:

Non-Small Cell Lung Cancer (NSCLC)

- A. Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC): AND
- B. Patient's disease is RET fusion-positive.

Medullary Thyroid Cancer

- A. Patient has a diagnosis of advanced or metastatic RET-mutant medullary thyroid cancer (MTC); AND
- B. Patient requires systemic therapy.

Thyroid Cancer

- A. Patient has a diagnosis of advanced or metastatic RET fusion-positive thyroid cancer; AND
- B. Patient requires systemic therapy; AND
- C. Patient is radioactive iodine-refractory (if radioactive iodine is appropriate).

References:

1. Retevmo™ capsules [prescribing information]. Indianapolis, IN: Eli Lilly and Company; May 2020.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 3.2020 – February 11, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on June 15, 2020.
3. The NCCN Thyroid Cancer Clinical Practice Guidelines in Oncology (Version 2.2019 – September 16, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on June 15, 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	06/15/2020