MEDICAL MUTUAL®

Drug Policy

Policy:	Retevmo (selpercatinib)	Annual Review Date: 06/18/2020 Last Revised Date: 06/18/2020

OVERVIEW

Retevmo is a kinase inhibitor indicated for the treatment of:

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

These 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 trials.

POLICY STATEMENT

This policy involves the use of Retevmo. Prior authorization is recommended for pharmacy benefit coverage of Retevmo. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Retevmo as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Retevmo be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Retevmo must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. <u>RET Fusion-Positive Non-Small Cell Lung Cancer (NSCLC)</u>
Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older; AND
B. The patient has metastatic disease.

2. **RET-Mutation Positive Medullary Thyroid Cancer**
Criteria. *Patient must meet the following criteria*

A. The patient is 12 years of age or older; AND
B. The patient has metastatic or advanced disease; AND
C. The patient requires systemic therapy.

3. **RET Fusion-Positive Thyroid Cancer**
Criteria. *Patient must meet the following criteria*

A. The patient is 12 year of age or older; AND
B. The patient has metastatic or advanced disease; AND
C. The patient requires systemic therapy; AND
D. The patient is radioactive-iodine refractory (if radioactive iodine is appropriate).

4. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

5. **Patient has been started on Retevmo**
Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Retevmo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a

pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Retevmo [prescribing information]. Indianapolis, IN: Eli Lilly and Company; May 2020.
2. Selpercatinib. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 28 May 2020. Accessed 16 June 2020.
3. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on 16 June 2020.