UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Retevmo

Program	Prior Authorization
Medication	Retevmo™ (selpercatinib)
Markets in Scope	Arizona, California, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	7/2020
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

1. Background:

Retevmo (selpercatinib) 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; and 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).

This indication is 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).

The National Cancer Comprehensive Network (NCCN) guideline also recommends use of Retevmo as preferred single-agent therapy for recurrent, advanced, or metastatic disease in patients with *RET* rearrangement positive tumors.

2. Coverage Criteria:

A. Non-Small Cell Lung Cancer (NSCLC)

1. Initial Authorization

a. Retevmo will be approved based on **all** of the following criteria:

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Disease is **one** of the following:

(a) Recurrent
(b) Advanced
(c) Metastatic

-AND-

(3) Presence of *RET* gene fusion-positive or *RET* rearrangement positive tumors

Authorization will be issued for 12 months.

2. Reauthorization

a. Retevmo will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Retevmo therapy

Authorization will be issued for 12 months.

B. Thyroid Cancer

1. Initial Authorization

a. Retevmo will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of medullary thyroid cancer (MTC)

-AND-

(b) Disease is one of the following:
(i) Advanced
(ii) Metastatic

-AND-

(c) Disease has presence of *RET* gene mutation

-AND-

(d) Disease requires treatment with systemic therapy

-OR-

(2) **All** of the following:

(a) Diagnosis of thyroid cancer

-AND-

(b) Disease is one of the following:
(i) Advanced
(ii) Metastatic

-AND-

(c) Disease is *RET* gene fusion-positive

-AND-

(d) Disease requires treatment with systemic therapy

-AND-

(e) **One** of the following:
(i) Patient is radioactive iodine-refractory
(ii) Treatment with radioactive iodine is not appropriate

Authorization will be issued for 12 months.

2. Reauthorization

a. Retevmo will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Retevmo therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Retevmo** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Retevmo** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Retevmo therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Retevmo [package insert]. Indianapolis, IN: Eli Lilly and Company, May 2020..
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May 22, 2020

Program	Program type – Prior Authorization
Change Control	
7/2020	New program.