UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1320-2
Program	Prior Authorization/Notification
Medication	Retevmo™ (selpercatinib)
P&T Approval Date	7/2020, 7/2021
Effective Date	10/1/2021; Oxford only: 10/1/2021

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 single-agent therapy for RET fusion target for the treatment of the following histiocyctic neoplasms: Langerhans Cell Histiocytosis, Erdheim-Chester disease, and Rosai-Dorman disease..

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. **Coverage Criteria:**

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. 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.

C. 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.

D. Histiocytic Neoplasms

1. Initial Authorization

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

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

(a) Diagnosis of one of the following histiocytic neoplasms:
i. Langerhans Cell Histiocytosis
ii. Erdheim-Chester disease
iii. Rosai-Dorfman disease

-AND-

(b) Used for RET fusion target as a single agent

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.

E. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

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, January 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May 19, 2021.

Program	Prior Authorization/Notification – Retevmo™ (selpercatinib)
Change Control	
7/2020	New program.
7/2021	Annual review. Updated coverage criteria in accordance with NCCN guidelines.