UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1320-6
Program	Prior Authorization/Notification
Medication	Retevmo® (selpercatinib)
P&T Approval Date	7/2020, 7/2021, 7/2022, 11/2022, 11/2023, 11/2024
Effective Date	2/1/2025

1. Background:

Retevmo (selpercatinib) is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic *rearranged during transfection (RET)* fusion-positive non-small cell lung cancer (NSCLC). Retevmo is also indicated, with approvals under accelerated approval, for the treatment of adult and pediatric patients 2 years of age and older with: advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy; advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate); and locally advanced or metastatic solid tumors with a RET gene fusion, as detected by an FDA-approved test, that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.[1]

Indications approved under accelerated approval are based on overall response rate and duration of response. Continued approval for these indications 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 histiocytic neoplasms: Langerhans Cell Histiocytosis, Erdheim-Chester disease, and Rosai-Dorfman 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]:

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. Solid Tumors

1. **Initial Authorization**

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

(1) Presence of *RET* gene fusion-positive solid tumor

-AND-

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

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

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.

F. 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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed October 3, 2024.

Program	Prior Authorization/Notification – Retevmo® (selpercatinib)
Change Control	
7/2020	New program.
7/2021	Annual review. Updated coverage criteria in accordance with NCCN guidelines.
7/2022	Annual review. Added state mandate with no other changes to coverage criteria. References updated.
11/2022	Updated background with traditional approval for locally advanced or metastatic NSCLC with a RET gene fusion per prescribing information. Updated background and added coverage for solid tumors with a *RET* gene fusion per prescribing information. Updated references.
11/2023	Annual review with no changes to clinical criteria. Updated reference.
11/2024	Annual review with no changes to clinical criteria. Updated background and references.