PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – RET-Targeting Agent) – Retevmo Prior Authorization Policy
- Retevmo® (selpercatinib capsules and tablets– Eli Lilly)

REVIEW DATE: 04/22/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Retevmo, a kinase inhibitor, is indicated for the following uses:[1]
- **Non-small cell lung cancer**, locally advanced or metastatic with a rearranged during transfection (*RET*) gene fusion, as detected by an FDA-approved test in adults.
- **Solid tumors,** locally advanced or metastatic solid tumors with a *RET* gene fusion in adult and pediatric patients ≥ 2 years of age who have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.
- **Thyroid cancer**, advanced or metastatic *RET*-mutant medullary, in adult and pediatric patients ≥ 2 years of age who require systemic therapy as detected by an FDA-approved test.
- **Thyroid cancer**, advanced or metastatic *RET* gene fusion-positive, in adult and pediatric patients ≥ 2 years of age who require systemic therapy and who are

radioactive iodine-refractory (if radioactive iodine is appropriate), as detected by an FDA-approved test.

The indication of *RET* gene fusion solid tumors was approved under accelerated approvals based on overall response rate and duration of response. Continued approval of this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Guidelines

Retevmo is addressed in the National Comprehensive Cancer Network (NCCN) compendium for a variety of solid tumors: appendiceal adenocarcinoma, endometrial carcinoma, occult primary, histiocytic neoplasms, ampullary adenocarcinoma, salivary gland tumors, pancreatic adenocarcinoma, soft tissue sarcoma, pheochromocytoma/paraganglioma, gastric cancer, breast cancer, esophageal and esophagogastric junction cancers, biliary tract cancer gallbladder cancer, intrahepatic/extrahepatic cholangiocarcinoma, hepatocellular cancer, ovarian cancer, colon and rectal cancer, small bowel adenocarcinoma, cervical cancer, uterine sarcoma, and vaginal cancer.[2] Retevmo is addressed in NCCN guidelines:

- **Histiocytic Neoplasms:** NCCN guidelines (version 2.2025 – November 21, 2025) recommend Retevmo as an agent that may be "Useful in Certain Circumstances" as the first- or subsequent-line treatment for the following types of histiocytic neoplasm with *RET* fusion: Langerhans cell histiocytosis, Erdheim-Chester disease, and Rosai-Dorfman disease (all category 2A).[3]
- **Non-Small Cell Lung Cancer:** NCCN guidelines (version 5.2026 – March 13, 2026) recommend Retevmo as a "preferred" option for first-line treatment of patients with *RET* rearrangement-positive recurrent, advanced, or metastatic non-small cell lung cancer (category 1).[2,4] Gavreto® (pralsetinib capsules) is also a "Preferred" first-line agent (category 2A). If *RET* rearrangement was discovered during first-line systemic therapy, interrupt current therapy and start Retevmo or Gavreto [both category 2A].
- **Thyroid Carcinoma:** NCCN guidelines (version 1.2025 – March 27, 2025) recommend Retevmo and Gavreto as "preferred regimens" for the treatment of *RET* pathogenic variant recurrent or persistent locoregional or metastatic medullary carcinoma (category 1).[5] Retevmo is also recommended for the treatment of locally recurrent, advanced, and/or metastatic *RET*-gene fusion positive thyroid carcinoma that is not amenable to radioactive iodine therapy as "Useful in Certain Circumstances" (category 2A). Additionally, NCCN recommends Retevmo for *RET*-fusion positive anaplastic thyroid carcinoma for locoregional disease and metastatic disease (category 2A).[5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Retevmo. All approvals are provided for the duration noted below.

- **Retevmo® (selpercatinib capsules and tablets - Eli Lilly)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has recurrent, advanced, or metastatic disease; AND
   C) The tumor is rearranged during transfection (*RET)* fusion-positive.

2. **Thyroid Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 2 years of age; AND
   B) Patient has rearranged during transfection (*RET)* fusion-positive, *RET* mutation-positive disease, or *RET* pathogenic variant; AND
   C) Patient meets ONE of the following (i or ii):
      i. Patient has anaplastic thyroid cancer; OR
      ii. The disease requires treatment with systemic therapy and patient meets ONE of the following (a or b):
         a) The patient has medullary thyroid cancer; OR
         b) The disease is radioactive iodine-refractory.

3. **Solid Tumors.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   Note: Examples of solid tumors include breast cancer, cervical cancer, cholangiocarcinoma, colorectal cancer, esophageal cancer, gastric cancer, ovarian cancer, pancreatic adenocarcinoma, salivary gland tumors, soft tissue sarcoma, small bowel adenocarcinoma, and unknown primary cancer.
   A) Patient is ≥ 2 years of age; AND
   B) Patient has recurrent, advanced, or metastatic disease; AND
   C) The tumor is rearranged during transfection (*RET)* fusion-positive.

Other Uses with Supportive Evidence

4. **Histiocytic Neoplasm.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following (i, ii, or iii):
      i. Patient has Langerhans cell histiocytosis; OR
      ii. Patient has Erdheim-Chester disease; OR
      iii. Patient has Rosai-Dorfman disease; AND
   C) Patient has a rearranged during transfection (*RET)* fusion.

CONDITIONS NOT COVERED

- **Retevmo® (selpercatinib capsules and tablets - Eli Lilly)**

is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Retevmo® tablets and capsules [prescribing information]. Indianapolis, IN: Eli Lilly and Company; November 2025.
2. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 20, 2026. Search term: selpercatinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 2.2025 – November 21, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 20, 2026.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2026 – March 13, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 20, 2026.
5. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 1.2025 – March 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 20, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	A new formulation of Retevmo tablets was added to the policy. The same criteria apply as those for the Retevmo capsules. **Thyroid Cancer:** Age requirement was changed from ≥ 12 years of age to ≥ 2 years of age due to expanded FDA labeled indication in pediatrics. The term "*RET* pathogenic variant" was added to criterion, "patient has rearranged during transfection (*RET)* fusion-positive, *RET* mutation-positive disease, or *RET* pathogenic variant." **Solid Tumors:** Age requirement was changed from ≥ 18 years of age to ≥ 2 years of age due to expanded FDA labeled indication in pediatrics.	06/05/2024
Update	The overview section was updated from accelerated approval language to full approval for the indication of advanced or metastatic RET fusion-positive thyroid cancer in adults and pediatric patients ≥ 2 years of age who are radioactive iodine-refractory, and require systemic therapy.	06/13/2024
Update	04/20/2025: The policy name was changed from "Oncology – Retevmo PA Policy" to "Oncology (Oral – Rearranged During Transfection-Targeting Agent) – Retevmo PA Policy".	N/A
Annual Revision	No criteria changes.	05/07/2025
Annual Revision	The policy name was changed from "Oncology (Oral – Rearranged During Transfection-Targeting Agent) – Retevmo" to "Oncology (Oral – RET-Targeting Agent) – Retevmo".	04/22/2026

N/A – Not applicable.