

Specialty Guideline Management

Retevmo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Retevmo	selpercatinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

- Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion.
- Adult and pediatric patients 2 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation who require systemic therapy.
- Adult and pediatric patients 2 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
- Adult and pediatric patients 2 years of age and older with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.

Compendial Uses²⁻⁷

- NSCLC - Recurrent or advanced

- Thyroid cancer
 - Locoregional or metastatic anaplastic thyroid carcinoma
 - Unresectable, recurrent, or persistent medullary thyroid cancer
 - Progressive and/or symptomatic oncocytic thyroid cancer
 - Progressive/symptomatic follicular and papillary thyroid cancer
- Solid tumors - recurrent, persistent, progressive, or unresectable
 - Appendiceal neoplasms and cancers
 - Breast cancer
 - Cervical cancer
 - Colorectal cancer, including anal adenocarcinoma
 - Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer
 - Esophageal and esophagogastric junction cancers
 - Gastric cancer
 - Intrahepatic and extrahepatic cholangiocarcinoma
 - Salivary gland tumors
 - Small bowel adenocarcinoma
 - Vaginal cancer
- Histiocytic Neoplasms
 - Erdheim-Chester Disease (ECD)
 - Rosai-Dorfman Disease
 - Langerhans Cell Histiocytosis (LCH)
- Occult primary cancer
- Gallbladder cancer
- Pancreatic adenocarcinoma
- Uterine neoplasms
 - Endometrial carcinoma
 - Uterine sarcoma
- Ampullary adenocarcinoma
- Soft tissue sarcoma
 - Extremity/body wall, head/neck sarcoma
 - Retroperitoneal/intra-abdominal sarcoma
 - Pleomorphic rhabdomyosarcoma
 - Phyllodes tumor of the breast
 - Epithelioid hemangioendothelioma
- Neuroendocrine and adrenal tumors
 - Extrapulmonary poorly differentiated: neuroendocrine carcinoma, large or small cell carcinoma, and mixed neuroendocrine-non-neuroendocrine neoplasm
 - Pheochromocytoma or paraganglioma

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: RET gene fusion or RET gene mutation testing results (where applicable).

Coverage Criteria

Non-Small Cell Lung Cancer (NSCLC)^{1,2}

Authorization of 12 months may be granted for treatment of RET gene fusion positive recurrent, advanced, or metastatic NSCLC, as a single agent.

Thyroid Cancer^{1,2}

Authorization of 12 months may be granted for treatment of RET gene mutated thyroid cancer, as a single agent, when any of the following criteria are met:

- Member has locoregional or metastatic anaplastic thyroid cancer
- Member has unresectable, recurrent, persistent, advanced, or metastatic medullary thyroid cancer
- Member has progressive, symptomatic, advanced, or metastatic oncocytic/Hurthle cell thyroid cancer
- Member has progressive, symptomatic, advanced, or metastatic follicular or papillary thyroid cancer that is not amenable to radioactive iodine therapy

Solid Tumors^{1,2,4-7}

Authorization of 12 months may be granted for treatment of RET gene fusion positive solid tumors, as a single agent, when all of the following criteria are met:

- The disease is recurrent, persistent, progressive, unresectable, advanced, or metastatic
- Member has not responded to preoperative therapy, has progressed on or following prior systemic treatment, or has no satisfactory alternative treatment options
- The member has one of the following solid tumors:
 - Appendiceal neoplasms and cancers
 - Breast cancer
 - Cervical cancer
 - Colorectal cancer, including anal adenocarcinoma
 - Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer
 - Esophageal and esophagogastric junction cancers
 - Gastric cancer

- Intrahepatic and extrahepatic cholangiocarcinoma
- Salivary gland tumors
- Small bowel adenocarcinoma
- Vaginal cancer

Histiocytic Neoplasms²

Authorization of 12 months may be granted for treatment of any of the following RET gene fusion positive histiocytic neoplasm subtypes, as a single agent:

- Symptomatic or relapsed/refractory Erdheim-Chester Disease (ECD)
- Symptomatic or relapsed/refractory Rosai-Dorfman Disease
- Langerhans Cell Histiocytosis (LCH)

Occult Primary Cancer²

Authorization of 12 months may be granted for treatment of RET gene fusion positive occult primary cancer that has progressed on or following systemic treatment, or there are no satisfactory alternative treatment options, as a single agent.

Gallbladder Cancer²

Authorization of 12 months may be granted for treatment of RET gene fusion positive gallbladder cancer, as a single agent, when either of the following criteria are met:

- The disease is unresectable, resected gross residual (R2), or metastatic and has progressed on or following systemic treatment
- The requested medication will be used as neoadjuvant therapy for resectable locoregionally advanced disease

Pancreatic Adenocarcinoma²

Authorization of 12 months may be granted for treatment of RET gene fusion positive locally advanced, recurrent, or metastatic pancreatic adenocarcinoma, as a single agent.

Uterine Neoplasms²

Authorization of 12 months may be granted for treatment of any of the following RET gene fusion positive uterine neoplasms subtypes, as a single agent:

- Recurrent or metastatic endometrial carcinoma, as subsequent therapy
- Advanced, recurrent/metastatic, or inoperable uterine sarcoma

Ampullary Adenocarcinoma²

Authorization of 12 months may be granted for treatment of RET gene fusion positive ampullary adenocarcinoma, as a single agent, when either of the following criteria are met:

- The disease is progressive
- The disease is metastatic and the requested medication will be used for first-line therapy

Soft Tissue Sarcoma^{2,3}

Authorization of 12 months may be granted for treatment of RET gene fusion positive advanced or metastatic soft tissue sarcoma (including extremity/body wall, head/neck, retroperitoneal/intra-abdominal sarcoma, pleomorphic rhabdomyosarcoma, borderline/malignant phyllodes tumor of the breast, and epithelioid hemangioendothelioma), as a single agent.

Neuroendocrine and Adrenal Tumors²

Authorization of 12 months may be granted for treatment of RET gene fusion positive locoregional unresectable or metastatic neuroendocrine and adrenal tumors, as a single agent, when both of the following criteria are met:

- The disease has progressed on or following systemic treatment, or there are no satisfactory alternative treatment options
- The requested medication will be used for either of the following:
 - Extrapulmonary poorly differentiated neuroendocrine carcinoma, large or small cell carcinoma, or mixed neuroendocrine-non-neuroendocrine neoplasm, as subsequent therapy
 - Pheochromocytoma or paraganglioma

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Retevmo [package insert]. Indianapolis, IN: Lilly USA, LLC; November 2025.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed March 13, 2026.

Reference number(s)
3874-A

3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma. Version 3.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed March 13, 2026.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf. Accessed March 13, 2026.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Biliary Tract Cancers. Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf. Accessed March 18, 2026.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer. Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed March 17, 2026.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers. Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed March 18, 2026.