

Retevmo (selpercatinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Retevmo (selpercatinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Retevmo (selpercatinib) may be approved if the following criteria are met:

- I. Individual has recurrent, advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) (Label, NCCN 2A); **AND**
 - A. Individual is using as monotherapy; **AND**
 - B. Individual has confirmation of RET fusion (or rearrangement) positive tumors; **AND**
 - C. Individual has not received treatment with another RET rearrangement positive-targeted agent, such as cabozantinib, vandetanib, or pralsetinib;

OR

- II. Individual has unresectable, recurrent, advanced or metastatic Medullary Thyroid Cancer (MTC) (Label, NCCN 2A); **AND**
 - A. Individual is 12 years of age or older; **AND**
 - B. Individual is using as monotherapy; **AND**
 - C. Individual has confirmation of RET mutation positive disease;

OR

- III. Individual has unresectable, recurrent, advanced or metastatic (non-medullary) Thyroid Cancer (Label, NCCN 2A); **AND**
 - A. Individual is 12 years of age or older; **AND**
 - B. Individual is using as monotherapy; **AND**
 - C. Individual has confirmation of RET fusion (or rearrangement) positive tumors; **AND**
 - D. Individual is radioactive iodine-refractory, or ineligible for radioactive iodine;

OR

- IV. Individual has a diagnosis of RET fusion positive NSCLC with limited or extensive brain metastases (NCCN 2A); **AND**
 - A. Individual has a primary diagnosis of RET fusion positive NSCLC; **AND**
 - B. Individual is using as single agent treatment;

OR

- V. Individual has locally advanced or metastatic solid tumors (Label, NCCN 2A); **AND**

- A. Individual has confirmation of RET gene fusion (or rearrangement) positive tumors; **AND**
- B. Individual is using as a single agent; **AND**
- C. Individual has progressed on or following prior systemic treatment OR who have no satisfactory alternative treatment options;

OR

- VI. Individual has a diagnosis for symptomatic or relapsed/refractory histiocytic neoplasms (Langerhans Cell Histiocytosis, Erdheim-Chester Disease or Rosai-Dorfman Disease) (NCCN 2A); **AND**
 - A. Individual is using as a single agent: **AND**
 - B. Individual has a RET fusion target.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 9, 2023
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Durham BH, Lopez Rodrigo E, Picarsic J, et al. Activating mutations in CSF1R and additional receptor tyrosine kinases in histiocytic neoplasms. Nat Med. 2019;25(12):1839-1842. doi:10.1038/s41591-019-0653-6 Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6898787/>. Accessed July 9, 2023.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 9, 2023.
 - a. Ampullary Adenocarcinoma. V1.2023. Revised April 27, 2023.
 - b. Biliary Tract Cancers. V2.2023. Revised May 10, 2023.
 - c. Breast Cancer. V4.2023. Revised March 23, 2023.
 - d. Central Nervous System Cancers. V1.2023. Revised March 24, 2023
 - e. Cervical Cancer. V1.2023. Revised April 28, 2023.
 - f. Colon Cancer. V2.2023. Revised April 25, 2023.
 - g. Esophageal and Esophagogastric Junction Cancers. V2.2023. Revised March 10, 2023.
 - h. Gastric Cancer. V1.2023. Revised March 10, 2023.
 - i. Head and Neck Cancers. V2.2023. Revised May 15, 2023.
 - j. Hepatocellular Carcinoma. V1.2023. Revised March 10, 2023.
 - k. Histiocytic Neoplasms. V1.2022. Revised May 20, 2022.
 - l. Neuroendocrine and Adrenal Tumors. V2.2022. Revised December 21, 2022.
 - m. Non-Small Cell Lung Cancer. V3.2023. Revised April 13, 2023.
 - n. Occult Primary. V3.2023. Revised December 21, 2022.
 - o. Ovarian Cancer. V2.2023. Revised June 2, 2023.
 - p. Pancreatic Cancer. V2.2023. Revised June 19, 2023.
 - q. Rectal Cancer. V3.2023. Revised May 26, 2023.
 - r. Small Bowel Adenocarcinoma. V1.2023. Revised January 9, 2023.
 - s. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
 - t. Thyroid Carcinoma. V2.2023. Revised May 18, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.