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 2 years of age or older; **AND**
   B. Individual is using as monotherapy; **AND**
   C. Individual has confirmation of RET mutation positive disease; **AND**
   D. Individual requires systemic therapy;

OR

III. Individual has unresectable, recurrent, advanced or metastatic (non-medullary) Thyroid Cancer (Label, NCCN 2A); **AND**
   A. Individual is 2 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; **AND**
   E. Individual requires systemic therapy;

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 treatment; **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.: 2024. 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 8, 2024.
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 8, 2024.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 8, 2024.
   a. Ampullary Adenocarcinoma. V1.2024. Revised December 13, 2023.
   b. Biliary Tract Cancers. V3.2024. Revised July 2, 2024.
   c. Breast Cancer. V4.2024. Revised July 3, 2024.
   d. Central Nervous System Cancers. V1.2024. Revised May 31, 2024.
   e. Cervical Cancer. V3.2024. Revised May 6, 2024.
   f. Colon Cancer. V4.2024. Revised July 3, 2024.
   g. Esophageal and Esophagogastric Junction Cancers. V3.2024. Revised April 26, 2024.
   h. Gastric Cancer. V2.2024. Revised May 29, 2024.
   i. Head and Neck Cancers. V4.2024. Revised May 1, 29=024.
   j. Hepatocellular Carcinoma. V2.2024. Revised July 2, 2024.
   k. Histiocytic Neoplasms. V1.2024. Revised March 15, 2024.
   l. Neuroendocrine and Adrenal Tumors. V1.2024. Revised June 20, 2024.
   m. Non-Small Cell Lung Cancer. V7.2024. Revised June 26, 2024.
   n. Occult Primary. V2.2024. Revised April 29, 2024.
   o. Ovarian Cancer. V2.2024. Revised May 13, 2024.
   p. Pancreatic Cancer. V2.2024. Revised April 30, 2024.
   q. Rectal Cancer. V3.2024. Revised July 3, 2024.
   r. Small Bowel Adenocarcinoma. V4.2024. Revised July 3, 2024.
   s. Soft Tissue Sarcoma.V1.2024. Revised April 26, 2024.
   t. Thyroid Carcinoma. V3.2024. Revised June 18, 2024.
   u. Vaginal Cancer. V1.2025. Revised March 25, 2024.