Rozlytrek (entrectinib)

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

Medications	Quantity Limit
Rozyltrek (entrectinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Rozyltrek (entrectinib) may be approved if the following criteria are met:

I. Individual has metastatic non-small cell lung cancer (NSCLC); **AND**
   A. Individual is 18 years of age or older; **AND**
   B. Individual is using as monotherapy (NCCN 2A); **AND**
   C. Individual's tumors are ROS1-positive; **AND**
   D. Individual has not received treatment with another ROS1 inhibitor (for example, crizotinib);

OR

II. Individual has a diagnosis of a solid tumor; **AND**
   A. Individual is 1 month of age or older; **AND**
   B. Individual is using as monotherapy; **AND**
   C. Individual's tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation; **AND**
   D. Individual's tumor is metastatic or where surgical resection is likely to result in severe morbidity; **AND**
   E. Individual has no satisfactory alternative treatments or has progressed following treatment; **AND**
   F. Individual has not received treatment with another NTRK inhibitor (for example, larotrectinib).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. 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: October 9, 2023
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. 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 October 9, 2023.
   a. Ampullary Adenocarcinoma. V2.2023. Revised August 3, 2023.
   b. Breast Cancer. V4.2023. Revised March 23, 2023.
   c. Biliary Tract Cancers. V2.2023. Revised May 10, 2023.

d. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
e. Cervical Cancer. V1.2024. Revised September 20, 2023.
f. Colon Cancer. V3.2023. Revised September 21, 2023.
g. Esophageal and Esophagogastric Junction Cancers. V3.2023. Revised August 29, 2023.
h. Gastric Cancer. V2.2023. Revised August 29, 2023.
i. Gastrointestinal Stromal Tumors (GISTs). V1.2023. Revised March 13, 2023.
j. Head and Neck Cancers. V1.2024. Revised October 9, 2023.
k. Hepatocellular Carcinoma. V2.2023. Revised September 14, 2023.
l. Histiocytic Neoplasms. V1.2023. Revised August 11, 2023.
m. Melanoma Cutaneous. V2.2023. Revised March 10, 2023.
n. Neuroendocrine and Adrenal Tumors. V1.2023. Revised August 2, 2023.
o. Non-Small Cell Lung Cancer. V3.2023. Revised April 13, 2023.
p. Occult Primary. V1.2023. Revised September 6, 2023.
q. Ovarian Cancer. V2.2023. Revised June 2, 2023.
r. Pancreatic Adenocarcinoma. V2.2023. Revised June 19, 2023.
s. Pediatric Central Nervous System Cancers. V2.2023. Revised October 31, 2022.
t. Rectal Cancer. V5.2023. Revised September 21, 2023.
u. Small Bowel Adenocarcinoma. V1.2023. Revised January 9, 2023.
v. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
w. Thyroid Carcinoma. V4.2023. Revised August 16, 2023.
x. Uterine Neoplasms. V1.2024. Revised September 20, 2023.
y. Vulvar Cancer V1.2024. Revised September 22, 2023.

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