



Commercial/Healthcare Exchange PA Criteria

Effective: November 22, 2019

Prior Authorization: Rozlytrek

Products Affected: Rozlytrek (entrectinib) oral capsules

Medication Description: Rozlytrek is an inhibitor of the tropomyosin receptor tyrosine kinases (TRK) TRKA, TRKB, and TRKC (encoded by the neurotrophic tyrosine receptor kinase [NTRK] genes NTRK1, NTRK2, and NTRK3, respectively) and proto-oncogene tyrosine-protein kinase ROS1 (ROS1).

Covered Uses:

1. Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1 positive
2. Adult and pediatric patients 12 years of age and older with solid tumors that:
 - a. Have a neurotrophic tyrosine kinase inhibitor (NTRK) gene fusion without a known acquired resistance mutation
 - b. Are metastatic or where surgical resection is likely to result in severe morbidity
 - c. Have progressed following treatment that have no satisfactory alternative therapy

Exclusion Criteria: N/A

Required Medical Information:

1. Metastatic NSCLC:
 - a. Diagnosis
 - b. ROS1 status
2. Solid Tumors:
 - a. Diagnosis
 - b. Positive NTRK gene fusion mutation without a known acquired resistance mutation
 - c. Previous therapies tried/failed

Age Restrictions:

1. Metastatic NSCLC: 18 years of age and older
2. Solid Tumors: 12 of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration: 3 years

Other Criteria:

Non-Small Cell Lung Cancer

- A. Patient has a diagnosis of Non-Small Cell Lung Cancer; AND
- B. Patient has ROS1-positive metastatic disease.



Solid Tumors

1. Patient’s tumor(s) have a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation; AND
2. Patient’s tumor(s) are metastatic OR where surgical resection is likely to result in severe morbidity; AND
3. The patient meets one of the following criteria (i or ii):
 - i. Patient has progressed on prior therapies OR
 - ii. There are no acceptable standard therapies and the medication is used as initial therapy.

References:

1. Rozlytrek [package insert]. South San Francisco, CA: Genentech USA; 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	11/19/2019