PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Rozlytrek Prior Authorization Policy
- Rozlytrek® (entrectinib capsules and oral pellets – Genentech)

REVIEW DATE: 09/27/2023; selected revision 11/22/2023

OVERVIEW

Rozlytrek, a kinase inhibitor, is indicated for the following uses:[1]

- **Non-small cell lung cancer (NSCLC)**, with *ROS1*-positive metastatic disease, as detected by an FDA-approved test, in adults.
- **Solid tumors**, in adult and pediatric patients ≥ 1 month of age that:
  - Have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion, as detected by an FDA-approved test without a known acquired resistance mutation; AND
  - Are metastatic or surgical resection of the tumor is likely to result in severe morbidity; AND
  - Have either progressed following treatment or there are no satisfactory alternative therapies.

Guidelines

Rozlytrek is addressed in guidelines by the National Comprehensive Cancer Network (NCCN):[2,3]

- **NSCLC.** Guidelines (version 3.2023 – April 13, 2023) recommend Rozlytrek as a preferred first-line treatment option for patients with *ROS1* rearrangement-positive NSCLC (category 2A).[2] Rozlytrek is also recommended as a preferred first-line treatment option for patients with *NTRK* gene fusion-positive NSCLC (category 2A).
- **Solid tumors.** The NCCN Drugs and Biologics Compendium notes the use of Rozlytrek for *NTRK* gene fusion-positive tumors associated with the following cancers: ampullary adenocarcinoma, breast cancer, central nervous system cancers (e.g., glioma, glioblastoma, brain metastases), cervical cancer, colon cancer, esophageal and esophagogastric junction cancers, gastric cancer, gastrointestinal stromal tumors, head and neck cancers (e.g., salivary gland tumors), hepatobiliary cancers, histiocytic neoplasms, melanoma (cutaneous), non-small cell lung cancer, ovarian cancer/fallopian tube cancer/primary peritoneal cancer, pancreatic cancer, rectal cancer, small bowel adenocarcinoma, soft tissue sarcomas, thyroid carcinoma, uterine neoplasms, and vulvar cancer.[3] Rozlytrek is a category 2A recommendation for most of these cancers. Rozlytrek is recommended for use as a first-line and/or second-line treatment option for these cancers.
- **Pediatric Central Nervous System Cancers.** Guidelines (version 2.2023 – October 31, 2022) recommend Rozlytrek as adjuvant therapy and for recurrent or progressive disease (category 2A for both), for *TRK* fusion-positive pediatric diffuse high-grade gliomas.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rozlytrek. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rozlytrek is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets the following (A, B, C, and D):
   Note: If the patient has non-small cell lung cancer with neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion, see **Solid Tumors** indication.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has metastatic disease; AND
   C) Patient has *ROS1*-positive disease; AND
   D) The mutation was detected by an approved test.

2. **Solid Tumors.** Approve for 1 year if the patient meets the following (A, B, and C):
   Note: Examples of solid tumors include breast cancer, colorectal cancer, head/neck cancer, hepatocellular carcinoma, biliary cancer, histiocytic neoplasm, non-small cell lung cancer (*NTRK* gene fusion-positive), ovarian cancer, pancreatic cancer, salivary gland tumors, sarcoma, thyroid cancer, adult glioma.
   A) Patient is ≥ 1 month of age; AND
   B) The tumor is positive for neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion; AND
   C) Patient meets one of the following (i or ii):
      i. The tumor is metastatic; OR
      ii. Surgical resection of tumor will likely result in severe morbidity.

Other Uses with Supportive Evidence

3. **Pediatric Diffuse High-Grade Gliomas.** Approve for 1 year if the patient meets the following (A, B, and C):
   A) Patient is < 18 years of age; AND
   B) The tumor is positive for neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion; AND
   C) Patient meets one of the following (i or ii):
      i. The medication is used as adjuvant therapy; OR
      ii. The medication is used for recurrent or progressive disease.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rozlytrek is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Rozlytrek® capsules and oral pellets [prescribing information]. South San Francisco, CA: Genentech; October 2023.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – April 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 25, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 12, 2023. Search term: entrectinib.