

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Rozlytrek Prior Authorization Policy

- Rozlytrek™ (entrectinib capsules – Genentech)

REVIEW DATE: 08/26/2020

OVERVIEW

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

- **Non-small cell lung cancer (NSCLC)**, for the treatment of adults with metastatic ROS1-positive disease.
- **Solid tumors**, treatment of adult and pediatric patients ≥ 12 years of age that a) have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation, b) are metastatic or where surgical resection is likely to result in severe morbidity, and c) have either progressed following treatment or have no satisfactory alternative therapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) Compendium recommends the use of Rozlytrek for *NTRK* gene fusion-positive tumors in the following disease states:² pancreatic cancer, colon and rectal cancer, breast cancer, cutaneous melanoma, cervical cancer, squamous cell carcinoma, endometrial cancer, uterine sarcoma, several types of soft tissue sarcoma, hepatocellular/biliary tract/gallbladder carcinoma, brain metastases, NSCLC, ovarian cancer, salivary gland tumors, esophageal/esophagogastric junction cancers, gastric cancer, and thyroid cancer. It is also recommended for ROS1 rearrangement-positive NSCLC. Rozlytrek is a category 2A recommendation for most cancers.

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 the following criteria:

FDA-Approved Indications

1. **Solid Tumors.** Approve for 3 years if the patient meets the following criteria (A, B, C, and D):
 - A) Patient is ≥ 12 years of age; AND
 - B) Patient's tumor has neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation; AND
 - C) Patient meets one of the following criteria (i or ii):
 - i. The tumor is metastatic; OR
 - ii. Surgical resection of tumor will likely result in severe morbidity; AND
 - D) Patient meets one of the following criteria (i or ii):
 - i. Patient has progressed following treatment; OR
 - ii. There are no satisfactory alternative therapies.

2. **Non-Small Cell Lung Cancer.** Approve for 3 years if the patient has *ROS1*-positive metastatic 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 [prescribing information]. South San Francisco, CA: Genetech; August 2019.
2. The NCCN Drugs & Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed August 24, 2020. Search terms: entrectinib.