MEDICAL MUTUAL®

Drug Policy

Policy:	Rozlytrek (entrectinib)	Annual Review Date: 09/21/2023 Last Revised Date: 09/21/2023

OVERVIEW

Rozlytrek is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive; adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy. This indication was approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

POLICY STATEMENT

This policy involves the use of Rozlytrek. Prior authorization is recommended for pharmacy benefit coverage of Rozlytrek. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Rozlytrek as well as the monitoring required for adverse events and long-term efficacy, approval requires Rozlytrek be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Rozlytrek must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Non-Small Cell Lung Cancer.** Approve in adults for 1 year if the patient has *ROS1*-positive metastatic disease.

2. **Solid Tumors.** Approve for 1 year 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.

3. **Patient has been started on Rozlytrek**
   Criteria. *Approve for an indication or condition addressed as an approval in this document if the patient has not experienced intolerable side effects and has had a beneficial response to therapy, per the prescribing physician*.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Rozlytrek has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Rozlytrek [prescribing information]. South San Francisco, CA; Genentech. August 2019.

2. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network Inc. Available at: http://www.nccn.org. Accessed on 13 September 2021.
3. Entrectinib. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 17 August 2021. Accessed on 13 September 2021.