



PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Rozlytrek™ (entrectinib capsules – Genentech)

TAC APPROVAL DATE: 08/16/2019; updated 08/21/2019

OVERVIEW

Rozlytrek, a kinase inhibitor, is indicated for the treatment of adult and pediatric patients ≥ 12 years of age 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 either progressed following treatment or have no satisfactory alternative therapy.

Rozlytrek is also approved for the treatment of adults with metastatic ROS1-positive non-small cell lung cancer (NSCLC).

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)** The patient is ≥ 12 years of age; AND
 - B)** The patient's tumor has neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation; AND
 - C)** The 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)** The patient meets one of the following criteria (i or ii):
 - i.** The 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

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.

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.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
New Policy	New criteria	08/16/2019
Update to New Policy	Updated criteria to match the FDA label	08/21/2019

TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>.