

Applicable Drugs: Rozlytrek (entrectinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/24/2019

Date Last Reviewed / Revised: 11/17/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met.)

- I. Documented of one of the following diagnoses A or B AND must meet all criteria listed under the applicable diagnosis:
FDA-Approved Indication(s)
 - A. Advanced, recurrent, or metastatic non-small cell lung cancer (NSCLC).
 - i. Age $\geq$ 18 years old with documentation of C-ros oncogene (ROS1) positive tumor biomarker testing.
 - B. Solid cancer tumors (breast, central nervous system, colorectal, gynecological, esophageal, gastric, salivary, hepatocellular, melanoma, NSCLC, neuroendocrine, sarcoma, thyroid, etc.) and meets i and ii: .
 - i. Age $\geq$ 12years old with documentation of positive neurotrophic tyrosine receptor kinase (NTRK) gene fusion biomarker testing without a known acquired resistance mutation.
 - ii. Documentation of tumors being unresectable, metastatic, recurrent, or without satisfactory alternative therapy.
- II. Treatment is prescribed by or in consultation with an oncologist or a hematologist.
- III. Documentation of assessment of left ventricular ejection fraction (LVEF) In patients with symptoms or known risk factors for congestive heart failure.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of Preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Pregnancy
- Lactation

- Severe renal impairment ($\text{CrCl} < 30 \text{ mL/min}$)
- Moderate (total bilirubin > 1.5 to 3 times the upper limit of normal (ULN) or severe (total bilirubin > 3 times ULN) hepatic impairment.

OTHER CRITERIA

N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Adults: ninety 200 mg capsules per 30 days.
- Pediatrics: sufficient capsules or pellets to comprise required daily dose per 30 days.
 - Age 1 month to 6 months: 250 mg/m^2 once daily
 - Age > 6 months:
 - $\leq 0.50 \text{ m}^2$: 300 mg/m^2 once daily
 - 0.51 to 0.80 m^2 : 200 mg once daily
 - 0.81 to 1.10 m^2 : 300 mg once daily
 - 1.11 to 1.50 m^2 : 400 mg once daily
 - $\text{BSA} \geq 1.51 \text{ m}^2$: 600 mg once daily
- Rozlytrek is available in 100 mg and 200 mg capsules, as well as oral pellets (50 mg per packet).

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** Updated letter of necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.