

Generic Name: Entrectinib

Therapeutic Class or Brand Name: Kinase inhibitor - Rozlytrek®

Applicable Drugs (if Therapeutic Class): Click or tap here to enter text.

GPI Code: 21533820000120

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/24/2019

Date Last Reviewed / Revised: 9/24/2019

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I-IV are met)

- I. Documented diagnosis of one of the following conditions A through B and must meet criteria listed under the applicable diagnosis:
 - A. Metastatic non-small cell lung cancer (NSCLC) whose tumors are *ROS-1* positive and the following criteria is met:
 1. 18 years of age and older
 - B. Neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion solid tumors when criteria 1 - 4 are met:
 1. 12 years of age and older with solid tumors
 2. Have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without known resistance mutations.
 3. Are metastatic or where surgical resection will result in severe morbidity.
 4. Have progressed following treatment or have no alternative therapy.
- II. In patients with symptoms or known risk factors of Congestive Heart Failure (CHF), assess left ventricular ejection fraction (LVEF).
- III. The prescribing physician is an oncologist.

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity of 30 capsules per 30 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. Medi-Span.
2. Rozlytrek® [Package insert] San Francisco, CA: Genentech, Inc.; 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212725s000lbl.pdf

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

| Date | Notes/Changes |
|-----------|----------------|
| 9/24/2019 | 1. New Policy. |

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.