

SPECIALTY GUIDELINE MANAGEMENT

ROZLYTREK (entrectinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Solid tumors
Rozlytrek is indicated for the treatment of adult and pediatric patients 12 years and older with solid tumors 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 no satisfactory alternative treatments or that have progressed following treatment.
2. Non-small cell lung cancer
Rozlytrek is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: NTRK gene fusion status or ROS1 status (where applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. Solid tumors

Authorization of 12 months may be granted for treatment of solid tumors when the tumors have a NTRK gene fusion without a known acquired resistance mutation, as demonstrated by laboratory testing (e.g., next-generation sequencing [NGS] or fluorescence in situ hybridization [FISH]).

B. Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic NTRK gene fusion-positive or ROS1-positive NSCLC as a single agent.

IV. CONTINUATION OF THERAPY

Reference number(s)
3165-A

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Rozlytrek [package insert]. South San Francisco, CA: Genentech, Inc. August 2019.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed July 2, 2021.