

**ROZLYTREK
(entrectinib)**

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Metastatic Non-Small Cell Lung Cancer (NSCLC)
 - a. 18 years of age or older
 - b. ROS1-positive as detected by an FDA-approved test
2. NTRK Gene Fusion-Positive Solid Tumors with **ALL** of the following:
 - a. 1 month of age or older
 - b. Neurotrophic tyrosine receptor kinase (NTRK) gene fusion as detected by an FDA-approved test without a known acquired resistance mutation
 - c. Metastatic **OR** surgical resection is likely to result in severe morbidity
 - d. Patient has progressed following treatment **OR** patient has no satisfactory alternative therapy

AND ALL of the following for **ALL** diagnoses:

1. Prescriber agrees to monitor AST and ALT
2. Prescriber agrees to monitor for QTc prolongation
3. Prescriber agrees to monitor for signs and symptoms of congestive heart failure (CHF)
4. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for at least 5 weeks after the last dose
5. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for at least 3 months after the last dose

Prior - Approval Limits

Quantity 600 mg per day

Duration 12 months

**ROZLYTREK
(entrectinib)**

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Metastatic Non-Small Cell Lung Cancer (NSCLC)
 - a. 18 years of age or older
2. NTRK Gene Fusion-Positive Solid Tumors with **ALL** of the following:
 - a. 1 month of age or older

AND ALL of the following for **ALL** diagnoses:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor AST and ALT
3. Prescriber agrees to monitor for QTc prolongation
4. Prescriber agrees to monitor for signs and symptoms of CHF
5. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for at least 5 weeks after the last dose
6. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for at least 3 months after the last dose

Prior - Approval *Renewal* Limits

Same as above