



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENTRECTINIB

Generic	Brand	HICL	GCN	Exception/Other
ENTRECTINIB	ROZLYTREK	45952		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has *ROS1*-positive tumors

If yes, **approve for 12 months by GPID for all strengths as follows:**

- **Rozlytrek 100mg: #5 per day.**
- **Rozlytrek 200mg: #3 per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of solid tumor and meet **ALL** of the following criteria?

- The patient is 12 years of age or older
- The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation
- The tumor is metastatic or surgical resection is likely to result in severe morbidity
- There are no satisfactory alternative treatments, or the patient has progressed following treatment

If yes, **approve for 12 months by GPID for all strengths as follows:**

- **Rozlytrek 100mg: #5 per day.**
- **Rozlytrek 200mg: #3 per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ENTRECTINIB (Rozlytrek)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC) or solid tumor. In addition, the following criteria must be met:

For a diagnosis of metastatic non-small cell lung cancer (NSCLC), approval requires:

- The patient is 18 years of age or older
- The patient has *ROS1*-positive tumors

For a diagnosis of solid tumor, approval requires:

- The patient is 12 years of age or older
- The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation
- The tumor is metastatic or surgical resection is likely to result in severe morbidity
- There are no satisfactory alternative treatments, or the patient has progressed following treatment

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rozlytrek.

REFERENCES

- Rozlytrek [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/20

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P&T Approval: 10/19