

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Rozlytrek (entrectinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Rozlytrek (entrectinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Rozlytrek (entrectinib) may be approved if the following criteria are met:

- I. Individual has metastatic non-small cell lung cancer (NSCLC); **AND**
 - A. Individual is 18 years of age or older; **AND**
 - B. Individual is using as monotherapy (NCCN 2A); **AND**
 - C. Individual's tumors are ROS1-positive (genetic test results confirmed); **AND**
 - D. Individual has not received treatment with another ROS1 inhibitor (for example, crizotinib); **AND**
 - E. Individual has a current ECOG performance status of 0-2.

OR

- II. Individual has a diagnosis of a solid tumor; **AND**
 - A. Individual is 12 years of age or older; **AND**
 - B. Individual's tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation (genetic test results confirmed); **AND**
 - C. Individual's tumor is metastatic or where surgical resection is likely to result in severe morbidity; **AND**
 - D. Individual has no satisfactory alternative treatments or has progressed following treatment; **AND**
 - E. Individual has not received treatment with another NTRK inhibitor (for example, larotrectinib); **AND**
 - F. Individual has a current ECOG performance status of 0-2.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

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New Program Date 10/11/2019

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	X	X	X	X	X

2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 20, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. National Cancer Institute. National Institutes of Health website. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/796818>. Accessed: September 20, 2019.

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