UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2021 P 1297-3 |
| Program | Prior Authorization/Notification |
| Medication | Rozlytrek™ (entrectinib) |
| P&T Approval Date | 10/2019, 10/2020, 10/2021 |
| Effective Date | 2/1/2022;<br>Oxford only: 2/1/2022 |

## 1. Background:

Rozlytrek (entrectinib) is a kinase inhibitor indicated for the treatment of:

- Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive.
- Adult and pediatric patients 12 years of age and older with solid tumors that:
  - Have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation,
  - Are metastatic or where surgical resection is likely to result in severe morbidity, and
  - Have progressed following treatment or have no satisfactory alternative therapy

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

**Coverage Information:**
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

## 2. Coverage Criteria:

**A. <u>Patients less than 19 years of age</u>**

1. **Rozlytrek** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   **Authorization will be issued for 12 months.**

**B. Non-small cell lung cancer (NSCLC)**

**1. Initial Authorization**

**a. Rozlytrek** will be approved based on **all** of the following criteria:

(1) Diagnosis of metastatic non-small cell lung cancer (NSCLC)

**-AND-**

(2) Disease is *ROS1*-positive

**Authorization will be issued for 12 months.**

**2. Reauthorization**

**a. Rozlytrek** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Rozlytrek therapy

**Authorization will be issued for 12 months.**

**C. Solid Tumors**

**1. Initial Authorization**

**a. Rozlytrek** will be approved based on **all** of the following criteria:

(1) Presence of solid tumors (e.g., sarcoma, NSCLC, salivary, breast, thyroid, colorectal, neuroendocrine, pancreatic, gynecological, cholangiocarcinoma, etc.)

**-AND-**

(2) Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g., *ETV6-NTRK3*, *TPM3-NTRK1*, *LMNA-NTRK1*, etc.)

**-AND-**

(3) Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

**-AND-**

(4) Disease is **one** of the following:

(a) Metastatic
(b) Unresectable

**-AND-**

(5) **One** of the following:

(a) Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy)
(b) Disease has no satisfactory alternative treatments

**Authorization will be issued for 12 months.**

**2. Reauthorization**

**a. Rozlytrek** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Rozlytrek therapy

**Authorization will be issued for 12 months.**

**D. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

**Authorization will be issued for 12 months.**

## 3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

## 4. References:


1. Rozlytrek [package insert]. Genentech USA, Inc.: South San Francisco, CA; August 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 19, 2021.


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| **Change Control** | |
| 10/2019 | New program. |
| 10/2020 | Annual review. No changes to clinical criteria. |
| 10/2021 | Annual review with no changes to clinical criteria. Updated references. |