UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Rozlytrek

Program	Prior Authorization
Medication	Rozlytrek™ (entrectinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	10/2019
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

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.

2. Coverage Criteria:

A. <u>Non-small cell lung cancer (NSCLC)</u>

1. <u>Initial Authorization</u>

a. Rozlytrek will be approved based on **<u>all</u>** of the following:

(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.

B. ***NTRK* gene fusion-positive 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.

C. NCCN Recommended Regimens

1. **Initial Authorization**

a. **Rozlytrek** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Rozlytrek therapy.

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 September9, 2020.

Program	Prior Authorization
Change Control	
Date	Change
10/2019	New program
10/2020	Annual review. No changes to clinical criteria. Updated reference. Added Additional Clinical Rules section.