POLICY NUMBER UM ONC_1367	SUBJECT Rozlytrek™ (entrectinib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 09/11/19, 12/11/19, 04/08/20	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 09/11/19, 12/11/19, 04/08/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

To define and describe the accepted indications for Rozlytrek (entrectinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**

b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**

c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies: **Error! Hyperlink reference not valid. AND**

d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**

e. When available, generic alternatives are preferred over brand-name drugs.

2. NTRK-Fusion Positive Metastatic Solid Tumors

a. **NOTE: The preferred agent, per NCH Policy & NCH Pathway, for NTRK gene fusion positive recurrent, advanced, or metastatic solid tumors is Rozlytrek (entrectinib) over Vitrakvi (larotrectinib).**

b. All the following criteria should be met:

i. Member has recurrent/metastatic/unresectable sold tumor with a positive NTRK fusion in the tumor tissue (test confirmation required) **AND**

ii. Member has experienced disease progression on standard/conventional systemic therapy.

3. Non-small cell lung cancer (NSCLC)

a. **NOTE: The preferred agent, per NCH Policy and NCH Pathway, for first line therapy of ROS1 positive NSCLC with CNS metastases is Rozlytrek (entrectinib); for members without CNS metastases, the preferred agent is Zalkori (crizotinib).**

b. The member has recurrent, advanced or metastatic NSCLC and Rozlytrek (entrectinib) is being used as a single agent in members with any of the following:

i. ROS1 rearrangement-positive tumors with CNS metastases as first-line therapy , or with ROS 1 rearrangement with/without CNS metastases for subsequent line therapy **OR**

ii. In members with NTRK gene fusion-positive tumors as subsequent therapy following progression on standard/conventional therapy (e.g. Chemotherapy, etc).

III. EXCLUSION CRITERIA

1. Off-label indications for Rozlytrek (entrectinib) in soft tissue sarcoma, occult primary, head and neck cancers, thyroid cancers, pancreatic adenocarcinoma, and ovarian cancers.
2. Rozlytrek (entrectinib) use after disease progression with the same regimen or other NTRK-targeted therapy.
3. Concurrent use with other ROS-1/ALK inhibitor (e.g. Crizotinib, ceritinib, alectinib, brigatinib, or lorlatinib) or NTRK inhibitor (e.g. Larotrectinib).
4. Dosing exceeds single dose limit of Rozlytrek (entrectinib) 600 mg.
5. Treatment exceeds the maximum limit of 30 (100 mg) and 60 (200 mg) tablets/month.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

I. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

II. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

III. ATTACHMENTS

None

IV. REFERENCES

1. Rozlytrek PI prescribing information. Genentech Inc South San Francisco, CA 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.