

**Neurotropic Receptor Tyrosine Kinase (NTRK) Gene Fusion**  
**Vitrakvi®**  
**Rozyltrek®**  
**Effective 01/01/2021**

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

**Overview**

VITRAKVI is a kinase inhibitor indicated for the treatment of adult and pediatric patients with solid tumors that:

- have a neurotrophic receptor tyrosine 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 no satisfactory alternative treatments or that have progressed following treatment.

ROZLYTREK is a kinase inhibitor indicated for the treatment of:

- Adult patients with metastatic non-small cell lung cancer (NSCLC) that is *ROS1*-positive. (1.1)
- 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.

Drugs that require PA	No PA
Rozyltrek® (entrectinib) and QL >30 capsules/month	Alternatives vary by disease category and may include systemic chemotherapy, radiation, or surgical intervention. Please refer to the NCCN guidelines for the most up-to-date recommendations.
Vitrakvi® (larotrectinib) and QL >60 capsules/month and >300 mL/month	

NCCN=National Comprehensive Cancer Network, PA=prior authorization



### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with the requested drugs, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

**OR**

Authorization may be granted if the member meets all following criteria and documentation has been submitted:

#### **Solid tumors with neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation (Rozlytrek<sup>®</sup>, Vitrakvi<sup>®</sup>)**

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
  - a. Tumor is metastatic
  - b. Member is not a candidate for surgical resection
5. **ONE** of the following:
  - a. Requested agent is first line for the requested indication
  - b. Member has no satisfactory alternative treatments options
  - c. Disease has progressed following at least one first-line treatment for the requested indication (e.g., chemotherapy, radiation, surgical intervention)
6. If request is for oral solution formulation, medical necessity for the use of an oral solution formulation (e.g. swallowing disorder)

#### **ROS1-positive metastatic non-small cell lung cancer (NSCLC) (Rozlytrek<sup>®</sup>)**

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Cancer is ROS1 positive (Documentation must be provided on the PA request or in attached medical records)

### Continuation of Therapy

Reauthorization requires documentation of positive response to therapy

### Limitations

1. Initial authorization may be issued for **3 months**
2. Reauthorization may be issued for **6 months**
3. The following quantity limits apply:

Rozlytrek	60 capsules per 30 days
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### References

1. ROZLYTREK<sup>®</sup> [prescribing information]. South San Francisco, CA: Genentech USA, Inc. 2019.
2. Vaishnavi A, Le AT, Doebele RC. TRKking down an old oncogene in a new era of targeted therapy. *Cancer Discov.* 2015;5(1):25-34.
3. VITRAKVI [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; July 2019.



4. Amatu A, Sartore-Bianchi A, Siena S. *NTRK* gene fusions as novel targets of cancer therapy across multiple tumour types. *ESMO Open*. 2016;1(2):e000023.
5. Laetsch TW, DuBois SG, Mascarenhas L, et al. Larotrectinib for paediatric solid tumours harbouring *NTRK* gene fusions: phase 1 results from a multicentre, open-label, phase 1/2 study. *Lancet Oncol*. 2018;19(5):705-714.

### **Review History**

10/6/20: Created criteria to follow MassHealth partial unified formulary; effective 1/1/21

### **Disclaimer**

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.