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

Plan
☐ MassHealth
☒ MassHealth (PUF)
☐ Commercial/Exchange

Program Type
☒ Prior Authorization
☐ Quantity Limit
☐ Step Therapy

Benefit
☒ Pharmacy Benefit
☐ Medical Benefit (NLX)

Specialty Limitations
This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

Specialty Medications
All Plans
Phone: 866-814-5506
Fax: 866-249-6155

Non-Specialty Medications
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

Medical Specialty Medications (NLX)
All Plans
Phone: 844-345-2803
Fax: 844-851-0882

Contact Information

Exceptions
N/A

Overview
VITRACKVI 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:
  o have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation,
  o are metastatic or where surgical resection is likely to result in severe morbidity, and
  o have progressed following treatment or have no satisfactory alternative therapy.

Drugs that require PA

<table>
<thead>
<tr>
<th>Drugs that require PA</th>
<th>No PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rozlytren® (entrectinib) and QL &gt;30 capsules/month</td>
<td>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.</td>
</tr>
<tr>
<td>Vitrakvi® (larotrectinib) and QL &gt;60 capsules/month and &gt;300 mL/month</td>
<td></td>
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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®, Vitrakvi®)**

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®)**

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:
   
<table>
<thead>
<tr>
<th>Drug</th>
<th>Limit</th>
</tr>
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<tbody>
<tr>
<td>Rozlytrek</td>
<td>60 capsules per 30 days</td>
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</tbody>
</table>

**References**


**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.