



PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 02/21/19  
LAST REVIEW DATE: 02/21/19  
LAST CRITERIA REVISION DATE:  
ARCHIVE DATE:

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## VITRAKVI® (larotrectinib) oral capsule & solution

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**

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## VITRAKVI® (larotrectinib) oral capsule & solution (cont.)

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### Criteria:

- **Criteria for initial therapy:** Vitrakvi (larotrectinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in or is in consultation with an Oncologist
  2. Individual is 28 days of age or older
  3. A confirmed diagnosis of **ONE** of the following:
    - As single-agent therapy for recurrent, advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) in patients with neurotrophic receptor tyrosine kinase (NTRK) gene fusion-positive tumors as first-line therapy **OR** subsequent therapy following progression on first-line systemic therapy with a non-NTRK-targeted regimen
    - As single agent for NTRK gene fusion positive sarcomas of extremity/superficial trunk, head/neck; or retroperitoneal/intra-abdominal; or non-pleomorphic rhabdomyosarcoma
    - Thyroid carcinoma (papillary, follicular, Hurthle cell) for NTRK gene fusion positive tumors, consider for treatment of structurally persistent/recurrent locoregional or distant metastatic disease not amenable to RAI therapy
    - Anaplastic thyroid carcinoma for NTRK gene fusion positive tumors, used as single agent therapy as aggressive therapy for metastatic disease
    - Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
  4. NTRK gene fusion is **without** a known acquired resistance mutation such as, G595R, G623R, G696A, or F617L
  5. Individual has metastatic disease or disease such that surgical resection is likely to result in severe morbidity
  6. There are no satisfactory alternative treatments or the disease has progressed following treatment
  7. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
    - Neurotrophic receptor tyrosine kinase (NTRK) gene fusion test
    - Pregnancy test in a woman of child bearing potential

**Initial approval duration:** 6 months

- **Criteria for continuation of coverage (renewal request):** Vitrakvi (larotrectinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in or is in consultation with an Oncologist

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2. Individual's condition has not worsened while on therapy
3. Individual has been adherent with the medication
4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
  - Significant adverse effect such as:
    - Severe neurotoxicity such as encephalopathy, severe gait disturbances, or delirium
    - Severe hepatotoxicity
    - Any adverse effect that has not resolved within 4 weeks of with-holding Vitrakvi
    - Individual who is unable to tolerate Vitrakvi after 3 dose modifications
5. There are no significant interacting drugs

**Renewal duration:** 12 months

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### **Description:**

Vitrakvi (larotrectinib) is an inhibitor of the tropomyosin receptor kinases (TRK), TRKA, TRKB, and TRKC. TRKA, B, and C are encoded by the genes *NTRK1*, *NTRK2*, and *NTRK3*. Chromosomal rearrangements involving fusions of these genes with other genes can result in constitutively-activated chimeric TRK fusion proteins that act as an oncogenic driver, promoting cell proliferation and survival in tumor cell lines.

NTRK fusions are rare but occur in sites where no other treatments are available for cancers that frequently express this mutation, like mammary analogue secretory carcinoma, cellular or mixed congenital mesoblastic nephroma and infantile fibrosarcoma.

Larotrectinib has minimal activity in cell lines with point mutations in the TRKA kinase domain, including the clinically identified acquired resistance mutation, G595R. Point mutations in the TRKC kinase domain with clinically identified acquired resistance to larotrectinib include G623R, G696A, and F617L.

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### **Resources:**

Vitrakvi product information accessed 02-11-19 at DailyMed:

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9525f887-a055-4e33-8e92-898d42828cd1>

NCCN Drugs & Biologics Compendium Vitrakvi accessed 02-11-19

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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Fax completed prior authorization request form to 602-864-3126 or email to [pharmacyprecert@azblue.com](mailto:pharmacyprecert@azblue.com).  
 Call 866-325-1794 to check the status of a request.  
 All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**  
 Pharmacy Coverage Guidelines are available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

# Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

**REQUIRED:** Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information		
Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information			
Medication Name:	Strength:	Dosage Form:	
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

Check if requesting **brand** only     Check if requesting **generic**

Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review	
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____	<input type="checkbox"/> Exigent (requires prescriber to include a written statement)

Clinical Information	
1. What is the diagnosis? Please specify below. ICD-10 Code: _____ Diagnosis Description: _____	
2. <input type="checkbox"/> Yes <input type="checkbox"/> No    Was this medication started on a recent hospital discharge or emergency room visit?	
3. <input type="checkbox"/> Yes <input type="checkbox"/> No    There is absence of ALL contraindications.	

4. What medication(s) has the individual tried and failed for this diagnosis? Please specify below.  
 Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. Are there any supporting labs or test results? Please specify below.

Date	Test	Value

# Pharmacy Prior Authorization Request Form

**6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.**  
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

**Signature affirms that information given on this form is true and accurate and reflects office notes**

Prescribing Provider's Signature:	Date:
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**Please note:** Some medications may require completion of a drug-specific request form.

**Incomplete forms or forms without the chart notes will be returned.**

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