TRAKAssist™
Access. Resources. Support.

*NTRK* Gene Fusion Diagnostic Testing Co-Pay Assistance

# Financial assistance for genetic diagnostic testing may be available for eligible patients with *NTRK* gene fusion

## To qualify for assistance with *NTRK* gene fusion diagnostic testing co-payments or coinsurance, you must meet the eligibility requirements:

- Valid VITRAKVI® (larotrectinib) prescription for an FDA-approved indication
- No insurance funded by state or federal government programs such as Medicare, Medicaid, VA/DoD health plans, or TRICARE
- Residency in the United States, including the District of Columbia, Puerto Rico, Guam, or the US Virgin Islands

## To apply for *NTRK* gene fusion diagnostic testing co-pay assistance, you must complete these steps:

- Complete the application, making sure to sign it
- **Insured patients:** attach or include Explanation of Benefits (EOB) or coverage denial letters from your insurance company
  – At least 2 attempts to appeal a denied claim are required
- **Cash patients:** attach or include a copy of your bill/receipt from the laboratory
- Mail the application and supporting documents to:

ConnectiveRx
Attn: Vitrakvi Diagnostic Testing Co-Pay Assistance Program
100 Passaic Ave., Suite 245
Fairfield, NJ 07004
or fax to: **1-833-270-4324**

## If you are approved, you will receive a one-time payment of up to $2,500 by check. You are responsible for paying any remaining balance due after co-pay assistance is provided.

## The TRAK Assist™ program offers a dedicated team of Care Coordinators available by phone to help support patient access to VITRAKVI

**Call 1-844-634-TRAK** (1-844-634-8725) 9:00 AM-7:00 PM ET, Monday-Friday

**Call TRAK Assist for:**

- Program questions
- Co-pay questions
- Information for additional financial support
- **Fax 1-888-506-TRAK** (1-888-506-8725)
- Visit VITRAKVI.com

Please see full Important Safety Information on page 2 and click here for full Prescribing Information.

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## Indication

VITRAKVI is 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.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

## Important Safety Information

**Neurotoxicity:** Among the 176 patients who received VITRAKVI, neurologic adverse reactions of any grade occurred in 53% of patients, including Grade 3 and Grade 4 neurologic adverse reactions in 6% and 0.6% of patients, respectively. The majority (65%) of neurologic adverse reactions occurred within the first three months of treatment (range 1 day to 2.2 years). Grade 3 neurologic adverse reactions included delirium (2%), dysarthria (1%), dizziness (1%), gait disturbance (1%), and paresthesia (1%). Grade 4 encephalopathy (0.6%) occurred in a single patient. Neurologic adverse reactions leading to dose modification included dizziness (3%), gait disturbance (1%), delirium (1%), memory impairment (1%), and tremor (1%).

Advise patients and caretakers of these risks with VITRAKVI. Advise patients not to drive or operate hazardous machinery if they are experiencing neurologic adverse reactions. Withhold or permanently discontinue VITRAKVI based on the severity. If withheld, modify the VITRAKVI dose when resumed.

**Hepatotoxicity:** Among the 176 patients who received VITRAKVI, increased transaminases of any grade occurred in 45%, including Grade 3 increased AST or ALT in 6% of patients. One patient (0.6%) experienced Grade 4 increased ALT. The median time to onset of increased AST was 2 months (range: 1 month to 2.6 years). The median time to onset of increased ALT was 2 months (range: 1 month to 1.1 years). Increased AST and ALT leading to dose modifications occurred in 4% and 6% of patients, respectively. Increased AST or ALT led to permanent discontinuation in 2% of patients.

Monitor liver tests, including ALT and AST, every 2 weeks during the first month of treatment, then monthly thereafter, and as clinically indicated. Withhold or permanently discontinue VITRAKVI based on the severity. If withheld, modify the VITRAKVI dosage when resumed.

**Embryo-Fetal Toxicity:** VITRAKVI can cause fetal harm when administered to a pregnant woman. Larotrectinib resulted in malformations in rats and rabbits at maternal exposures that were approximately 11- and 0.7-times, respectively, those observed at the clinical dose of 100 mg twice daily.

Advise women of the potential risk to a fetus. Advise females of reproductive potential to use an effective method of contraception during treatment and for 1 week after the final dose of VITRAKVI.

**Most Common Adverse Reactions (≥20%):** The most common adverse reactions (≥20%) were: increased ALT (45%), increased AST (45%), anemia (42%), fatigue (37%), nausea (29%), dizziness (28%), cough (26%), vomiting (26%), constipation (23%), and diarrhea (22%).

**Drug Interactions:** Avoid coadministration of VITRAKVI with strong CYP3A4 inhibitors (including grapefruit or grapefruit juice), strong CYP3A4 inducers (including St. John's wort), or sensitive CYP3A4 substrates. If coadministration of strong CYP3A4 inhibitors or inducers cannot be avoided, modify the VITRAKVI dose as recommended. If coadministration of sensitive CYP3A4 substrates cannot be avoided, monitor patients for increased adverse reactions of these drugs.

**Lactation:** Advise women not to breastfeed during treatment with VITRAKVI and for 1 week after the final dose.

Please click here for full Prescribing Information.

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# *NTRK* Gene Fusion Diagnostic Testing
# Co-Pay Assistance Form

This form is for reimbursement of VITRAKVI® (larotrectinib) patients' co-payment or out-of-pocket expenses directly incurred for *NTRK* gene fusion testing under the TRAK Assist™ *NTRK* Gene Fusion Diagnostic Testing Co-Pay Assistance Program (the Program) sponsored by Bayer. Patient cost-share obligations for office visits are not reimbursable under the Program. Payment of the reimbursement is subject to verification by Bayer in its sole discretion, as well as all the Terms and Conditions of the Program. Not valid for diagnostics covered by or submitted for reimbursement, in whole or part, under Medicare, Medicaid, TRICARE, and similar federal- or state-funded programs, or where otherwise prohibited by law. Bayer reserves the right to amend or terminate this program at any time without notice.

## BILLING LABORATORY INFORMATION REQUIRED*

LABORATORY NAME*

ADDRESS 1* | ADDRESS 2

CITY* | STATE* | ZIP CODE*

CONTACT PHONE NUMBER* | EMAIL ADDRESS

## ORDERING PHYSICIAN INFORMATION

FIRST NAME* | LAST NAME* | PHYSICIAN NPI* | PHONE NUMBER*

## PRIMARY PAYER INFORMATION

PAYER NAME* | GROUP#* | PHONE NUMBER* | SUBSCRIBER ID*

## PATIENT INFORMATION

FIRST NAME* | MIDDLE | LAST NAME* | ☐ Male ☐ Female GENDER*

ADDRESS 1* | ADDRESS 2

CITY* | STATE* | ZIP CODE* | PHONE NUMBER*

DATE OF BIRTH*

I hereby authorize and direct the Program to issue payment directly to: ☐ Billing Laboratory ☐ Patient Confirm the following:

☐ I understand it is my responsibility to pay my cost-share for my *NTRK* gene fusion diagnostic testing, including any remaining balance if I am eligible to receive a one-time co-pay assistance payment of up to $2,500.

PATIENT SIGNATURE* | DATE*

## REIMBURSEMENT PROCESS

- ✓ Complete the application, making sure to sign it
- ✓ **Insured patients:** include a copy of your prescription for VITRAKVI
  - If submitting denial letters, you must demonstrate at least 2 attempts of coverage before assistance can be offered
- ✓ **Cash patients:** include a copy of your bill/receipt from the laboratory
- ✓ If you are approved, you or the billing laboratory will receive a one-time payment of up to $2,500 by check. You are responsible for paying any remaining balance due after co-pay assistance is provided

Mail or fax the application and supporting documents to:

**Mail:** ConnectiveRx
Attn: Vitrakvi Diagnostic Testing Co-Pay Assistance Program
100 Passaic Ave., Suite 245
Fairfield, NJ 07004

**Fax:** 1-833-270-4324

**Phone:** 1-833-270-4323



VITRAKVI® (larotrectinib) 25-mg/100-mg CAPSULES 20-mg/mL ORAL SOLUTION