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

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.

Access Services by Bayer™ offers a dedicated team of Care Coordinators available by phone to help support patient access to VITRAKVI

Call 1-800-288-8374 8:00 AM-8:00 PM ET, Monday-Friday

Call Access Services by Bayer for:

- Program questions
- Co-pay questions
- Information for additional financial support
- Visit VITRAKVI.com

Access Services by Bayer™

Please see Important Safety Information on pages 2 to 3, 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 know 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.

Select patients for therapy based on an FDA-approved test.

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

Warnings and Precautions

- **Central Nervous System Effects:** Central nervous system (CNS) adverse reactions occurred in patients receiving VITRAKVI, including dizziness, cognitive impairment, mood disorders, and sleep disturbances.

  In patients who received VITRAKVI, all grades CNS effects including cognitive impairment, mood disorders, dizziness and sleep disorders were observed in 42% with Grades 3-4 in 3.9% of patients.

  Cognitive impairment occurred in 11% of patients. The median time to onset of cognitive impairment was 5.6 months (range: 2 days to 41 months). Cognitive impairment occurring in ≥ 1% of patients included memory impairment (3.6%), confusional state (2.9%), disturbance in attention (2.9%), delirium (2.2%), cognitive disorders (1.4%), and Grade 3 cognitive adverse reactions occurred in 2.5% of patients. Among the 30 patients with cognitive impairment, 7% required a dose modification and 20% required dose interruption.

  Mood disorders occurred in 14% of patients. The median time to onset of mood disorders was 3.9 months (range: 1 day to 40.5 months). Mood disorders occurring in ≥1% of patients included anxiety (5%), depression (3.9%), agitation (2.9%), and irritability (2.9%). Grade 3 mood disorders occurred in 0.4% of patients.

  Dizziness occurred in 27% of patients, and Grade 3 dizziness occurred in 1.1% of patients. Among the 74 patients who experienced dizziness, 5% of patients required a dose modification and 5% required dose interruption.

  Sleep disturbances occurred in 10% of patients. Sleep disturbances included insomnia (7%), somnolence (2.5%), and sleep disorder (0.4%). There were no Grade 3-4 sleep disturbances. Among the 28 patients who experienced sleep disturbances, 1 patient each (3.6%) required a dose modification or dose interruption.

  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 dosage when resumed.

- **Skeletal Fractures:** Among 187 adult patients who received VITRAKVI across clinical trials, fractures were reported in 7% and among 92 pediatric patients, fractures were reported in 9% (N=279; 8%). Median time to fracture was 11.6 months (range 0.9 to 45.8 months) in patients followed per fracture. Fractures of the femur, hip or acetabulum were reported in 4 patients (3 adult, 1 pediatric). Most fractures were associated with minimal or moderate trauma. Some fractures were associated with radiologic abnormalities suggestive of local tumor involvement. VITRAKVI treatment was interrupted due to fracture in 1.4% patients.

  Promptly evaluate patients with signs or symptoms of potential fracture (e.g., pain, changes in mobility, deformity). There are no data on the effects of VITRAKVI on healing of known fractures or risk of future fractures.

Please see additional Important Safety Information on page 3, and click here for full Prescribing Information.

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IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- **Hepatotoxicity:** Hepatotoxicity including drug induced liver injury (DILI) has been reported in patients taking VITRAKVI.

  In patients who received VITRAKVI, increased AST of any grade occurred in 52% of patients and increased ALT of any grade occurred in 45%. Grade 3-4 increased AST or ALT occurred in 3.1% and 2.5% of patients, respectively. The median time to onset of increased AST was 2.1 months (range: 1 day to 4.3 years). The median time to onset of increased ALT was 2.3 months (range: 1 day to 4.2 years). Increased AST and ALT leading to dose modifications occurred in 1.4% and 2.2% of patients, respectively. Increased AST or ALT led to permanent discontinuation in 3 (1.1%) of patients.

  There have been reports in adult patients from clinical studies and post-marketing cases of Grade ≥ 2 increases in ALT and/or AST with increases in bilirubin ≥ 2 x ULN.

  Obtain liver function tests (ALT, AST, ALP and bilirubin) before initiation of VITRAKVI and monitor every 2 weeks during the first two months of treatment, then monthly thereafter, or more frequently following the occurrence of Grade 2 or greater AST or ALT elevation. Temporarily withhold, reduce the dose, or permanently discontinue VITRAKVI based on severity.

- **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 last dose of VITRAKVI.

Adverse Reactions

- The most common adverse reactions (≥20%), including laboratory abnormalities, were: increased AST (52%), increased ALT (45%), anemia (42%), musculoskeletal pain (42%), fatigue (36%), hypoalbuminemia (36%), neutropenia (36%), increased alkaline phosphatase (34%), cough (32%), leukopenia (28%), constipation (27%), diarrhea (27%), dizziness (27%), hypocalcemia (25%), nausea (25%), vomiting (25%), pyrexia (24%), lymphopenia (22%) and abdominal pain (21%).

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. For coadministration with moderate CYP3A4 inhibitors, monitor for adverse reactions more frequently and reduce the dosage based on severity. For coadministration with moderate CYP3A4 inducers, modify dose as recommended.

Use in Specific Populations

- Lactation: Advise women not to breastfeed during treatment with VITRAKVI and for 1 week after the last 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 VITRAKVI *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: 1-844-634-8725

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