

Patient access and reimbursement support for VITRAKVI® (larotrectinib)

Access Services by Bayer™ can connect eligible VITRAKVI patients to available affordability support options. Call 1-800-288-8374 to learn more.

CALL



1-800-288-8374, anytime between 8:00 AM–8:00 PM ET, Monday–Friday

Call Access Services by Bayer for: Co-pay questions • Information for additional financial support

VISIT



VITRAKVIhcp.com

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.

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

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 40.3% with Grades 3-4 in 3.8% of patients.

Cognitive impairment occurred in 11% of patients. The median time to onset of cognitive impairment was 6 months (range: 2 days to 56 months). Cognitive impairment occurring in $\geq 1\%$ of patients included memory impairment (4.1%), disturbance in attention (3.6%), confusional state (2.3%), cognitive disorder (1.6%), delirium (1.4%), and hallucination (1.1%). Grade 3 cognitive adverse reactions occurred in 1.8% of patients and Grade 4 cognitive adverse reactions in 0.2% of patients. Among the 49 patients with cognitive impairment, 6% required a dose modification and 18% required dose interruption.

Mood disorders occurred in 14% of patients. The median time to onset of mood disorders was 3.3 months (range: 1 day to 65 months). Mood disorders occurring in $\geq 1\%$ of patients included anxiety (5%), agitation (3.2%), depression (3.2%), irritability (2.3%), and restlessness (1.1%). Grade 3 mood disorders occurred in 0.9% of patients. Among the 63 patients who experienced mood disorders, no patient required a dose modification, and 1.6% required dose interruption.

Dizziness occurred in 22% of patients, and Grade 3 dizziness occurred in 0.9% of patients. Among the 96 patients who experienced dizziness, 6% of patients required a dose modification and 5% required dose interruption.

Sleep disturbances occurred in 12% of patients. Sleep disturbances included insomnia (9%), somnolence (3.4%), and sleep disorder (0.5%). Grade 3 sleep disturbances occurred in 0.2% of patients.

Please see Important Safety Information throughout and click here for full [Prescribing Information](#).



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

VITRAKVI \$0 CO-PAY SAVINGS CARD

\$0 per month for VITRAKVI*

- Eligible commercial patients may pay as little as \$0 per month up to a program maximum for VITRAKVI*
- To activate the VITRAKVI Savings Card: Call 647-245-5637 or visit vitrakvicopaysupport.com
- Once activated, patients may present the card at the pharmacy, and the offer will be automatically applied



Bayer US Patient Assistance Foundation

If your patients cannot afford their prescription medication, Bayer may be able to help.

The Bayer US **Patient Assistance Foundation** is a charitable organization that helps eligible patients get their Bayer prescription medicine at no cost.

Please have your patient contact the program at **1-866-2BUSPAF (228-7723)** Monday–Friday, 9:00 AM to 6:00 PM ET, or visit the foundation website at www.patientassistance.bayer.us for information to see if they might qualify for assistance.



Bayer US **Patient Assistance Foundation**

*Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. As a condition precedent of the co-payment support provided under this program, e.g., co-pay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payers of any benefits they receive and the value of this program, as required by contract or otherwise. Void where prohibited by law, taxed, or restricted. Patients enrolled in the Bayer US Patient Assistance Foundation are not eligible. Bayer may determine eligibility, monitor participation, equitably distribute product and modify or discontinue any aspect of VITRAKVI \$0 Co-pay Program at any time, including but not limited to this commercial co-pay assistance program.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- **Central Nervous System Effects:** (continued): Among the 54 patients who experienced sleep disturbances, no patient required a dose modification and 3.7% required 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:** Skeletal fractures can occur in patients taking VITRAKVI.

Among 444 patients who received VITRAKVI across clinical trials, fractures occurred in 7% of patients; 6% of 290 adult patients and 10% of 154 pediatric patients. Median time to first fracture was 13 months (range 27 days to 73 months) in patients followed per fracture. The most common fractures were of the rib (1.4%), fibula, foot or wrist (0.7% each). 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 Important Safety Information throughout and click here for full [Prescribing Information](#).



Access Services by Bayer™ provides several options to help patients access their VITRAKVI® treatment



Comprehensive and Coordinated Support for Your Patients From Our In-Network Specialty Pharmacies

- A dedicated phone line provides patients taking VITRAKVI direct access to a nurse or pharmacist who can answer questions about treatment with VITRAKVI
 - These specialists will also triage patients back to their treating oncologist as appropriate
- Regularly scheduled outbound calls to provide information about:
 - VITRAKVI treatment
 - Understanding dosing for adults and pediatric patients
 - Signing up for optional text message refill reminders
 - Hospital-to-home order coordination



Accredo®: 1-855-540-1797

www.accredo.com

CVS Specialty™: 1-800-790-1698

www.cvsspecialty.com

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

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

In patients who received VITRAKVI (n=444), increased AST of any grade occurred in 62% of patients and increased ALT of any grade occurred in 61%. Grade 3-4 increased AST or ALT occurred in 7% and 8% of patients, respectively. The median time to onset of increased AST was 1.9 months (range: 4 days to 3.8 years). The median time to onset of increased ALT was 1.9 months (range: 1 day to 4.9 years). Increased AST and ALT leading to dose modifications occurred in 1.6% and 3.2% of patients, respectively. Increased AST or ALT led to permanent discontinuation in 4 (0.9%) patients.

There have been reports from clinical studies and postmarketing cases of Grade ≥ 2 increases in ALT and/or AST with increases in bilirubin $\geq 2 \times$ ULN.

Obtain liver function tests (ALT, AST, ALP and bilirubin) before initiation of VITRAKVI and monitor every 2 weeks during the first 2 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.

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

Ordering

VITRAKVI® (larotrectinib) is available from:

Specialty Pharmacy

Accredo	Phone: 1-855-540-1797 Fax: 1-877-327-7120 accredo.com	Mon–Fri 8:30 AM–9:00 PM EST
CVS Specialty	Phone: 1-800-790-1698 Fax: 1-855-296-0210 cvsspecialty.com	Mon–Fri 8:30 AM–8:30 PM EST

Specialty Distributor

Amerisource Bergen (ASD)	Phone: 1-800-746-6273 Fax: 1-800-547-9413 asdhealthcare.com	Mon–Thu 7:00 AM–6:30 PM CST Fri 7:00 AM–6:00 PM CST
Cardinal Health Specialty	Phone: 1-855-855-0708 Fax: 1-614-553-6301 cardinalhealth.com/en/services/specialty-physician-practice/specialty-distribution-services.html	Mon–Sun Open 24 hours
McKesson Specialty	Phone: 1-800-482-6700 Fax: 1-855-477-9800 mscs.mckesson.com	Mon–Fri 7:00 AM–7:00 PM CST
McKesson Plasma & Biologics	Phone: 1-877-625-2566 Fax: 1-888-752-7626 mckesson.com/pharmaceutical-distribution/plasma-biologics/	Mon–Fri 8:00 AM–6:30 PM CST
Oncology Supply	Phone: 1-800-633-7555 Fax: 1-800-248-8205 oncologysupply.com	Mon–Fri 8:00 AM–7:00 PM CST

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions

- The most common adverse reactions (≥20%), including laboratory abnormalities, were: increased AST (62%), increased ALT (61%), anemia (45%), hypoalbuminemia (44%), musculoskeletal pain (41%), increased alkaline phosphatase (40%), leukopenia (37%), lymphopenia (35%), neutropenia (34%), hypocalcemia (32%), fatigue (31%), vomiting (30%), cough (29%), constipation (27%), pyrexia (26%), diarrhea (26%), nausea (25%), abdominal pain (24%), dizziness (22%), and rash (21%).

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

Product Information

Storage and Handling¹



Store capsules at room temperature 20°C to 25°C (68°F to 77°F); temperature excursions between 15°C and 30°C (59°F to 86°F) are permitted.



Refrigerate oral solution at 2°C to 8°C (36°F to 46°F). Do not freeze.

How Supplied¹



25-mg capsules

NDC:
50419-390-01

Supplied in:
60-count bottle



100-mg capsules

NDC:
50419-391-01

Supplied in:
60-count bottle



20-mg/mL oral solution

NDC:
50419-392-01

Supplied in:
1 bottle of 100 mL



20-mg/mL oral solution

NDC:
50419-393-03

Supplied in:
2 bottles of 50 mL

NDC=National Drug Code.

IMPORTANT SAFETY INFORMATION (continued)

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.

Reference: 1. VITRAKVI [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; April 2025.

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