Access Services by Bayer™

Patient access and reimbursement support for VITRAKVI® (larotrectinib)

The Access Services by Bayer™ patient support program is committed to offering comprehensive access, reimbursement support, and patient assistance services.

CALL

1-800-288-8374, 9:00 AM–6:00 PM ET, Monday–Friday

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

FAX

1-800-390-1826

VISIT

VITRAKVI-US.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.
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.

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

Access Services by Bayer™

Access Services by Bayer™ provides access support and coverage assistance

Patient Coverage Support

- Insurance benefit investigation for VITRAKVI® (larotrectinib)
- Prior authorization (PA) and appeals support for VITRAKVI
- Sample documentation
- Payer policy information
- Prescription triage to a Bayer In-Network Specialty Pharmacy
- Verifying or facilitating enrollment in the VITRAKVI $0 Co-pay Program, if eligible*

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

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Central Nervous System Effects (continued): 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.

The Access Services by Bayer™ program offers a dedicated team of Care Coordinators available by phone to help support patient access to VITRAKVI® (larotrectinib)

Patient Access Support

- **VITRAKVI $0 Co-Pay Program** for eligible patients with commercial or private insurance*
- **Referrals to independent assistance foundations** for publicly insured patients who need help with out-of-pocket costs related to their treatment†
- **Referrals to the Bayer US Patient Assistance Foundation** for qualified uninsured or underinsured patients

Call 1-800-288-8374

(9:00 AM–6:00 PM ET, Monday–Friday)

Call Access Services by Bayer for:

- Program questions
- Co-pay questions
- Information for additional financial support

*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, eg, 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 the VITRAKVI $0 co-pay Program at any time, including but not limited to this commercial co-pay assistance program.

† Access Services by Bayer offers referrals to third-party assistance programs; eligibility criteria apply.

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Access Services by Bayer™

ORDER

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 7:30 AM–8:30 PM EST

Specialty Distributor		
Amerisource Bergen (ASD)	Phone: 1-800-746-6273 Fax: 1-800-547-9413 asdhealthcare.com	Mon–Thurs 7 AM–6:30 PM CST Fri 7 AM–6 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 AM–7 PM CST
McKesson Plasma & Biologics	Phone: 1-877-625-2566 Fax: 1-888-752-7626 mckesson.com/pharmaceutical-distribution/plasma-biologics/	Mon–Fri 8 AM–6:30 PM CST
Oncology Supply	Phone: 1-800-633-7555 Fax: 1-800-248-8205 oncologysupply.com	Mon–Sun 8 AM–7 PM CST

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Central Nervous System Effects (continued): 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.

PRODUCT

Product Information

Storage and Handling[1]

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 Supplied[1]

25-mg capsules	100-mg capsules	20-mg/mL oral solution	20-mg/mL oral solution
NDC: 50419-390-01	NDC: 50419-391-01	NDC: 50419-392-01	NDC: 50419-393-03
Supplied in: 60-count bottle	Supplied in: 60-count bottle	Supplied in: 1 bottle of 100 mL	Supplied in: 2 bottles of 50 mL

NDC=National Drug Code.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Central Nervous System Effects (continued): 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.

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

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- 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.
- 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.

IMPORTANT SAFETY INFORMATION (continued)

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.

Reference: VITRAKVI [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; December 2022.

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Your first step:

Contact Access Services by Bayer™

Get information on VITRAKVI® (larotrectinib) and Access Services by Bayer™ patient support services, including:

- ☑ Insurance benefit investigation for VITRAKVI
- ☑ Sample documentation, including Letters of Medical Necessity
- ☑ Prior authorization appeals support for VITRAKVI
- ☑ Payer policy information
- ☑ Prescription triage to a Bayer In-Network Specialty Pharmacy
- ☑ Bayer In-Network Specialty Pharmacy information and hospital-to-home order coordination
- ☑ Information about patient access support options

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