TRAK Assist™
Access. Resources. Support.

Patient access and reimbursement support for VITRAKVI® (larotrectinib)

The TRAK Assist™ patient support program is committed to offering comprehensive access, reimbursement support, and patient assistance services.

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

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.

(continued on page 2)

Please see full Important Safety Information throughout and click here for full Prescribing Information.

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

TRAKAssist™
Access. Resources. Support.

TRAK Assist™ 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
- Testing locations for Next-Generation Sequencing (NGS) for *NTRK* gene fusions
- Resources for diagnostic testing
- Prescription triage to a Bayer In-Network Specialty Pharmacy
- Hospital-to-home order coordination

Comprehensive and Coordinated Support for Your Patients

- 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
  - Verifying or facilitating enrollment in TRAK Assist $0 Co-Pay Program for VITRAKVI, if eligible*=

Important Safety Information (cont'd)

Neurotoxicity (cont'd): 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%).

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

Patient Access Support

- **TRAK Assist $0 Co-Pay Program for VITRAKVI** for eligible patients with commercial or private insurance*
- **VITRAKVI Bridge Program** for patients whose coverage is delayed or who experience a temporary lapse in coverage
  - Provides free VITRAKVI during the limited period without coverage
- **Referrals to independent assistance foundations** for publicly insured patients who need help with out-of-pocket costs related to their treatment†
- **Bayer US Patient Assistance Foundation** for qualified uninsured or underinsured patients

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

*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 TRAK Assist at any time, including but not limited to this commercial co-pay assistance program.

†TRAK Assist offers referrals to third-party assistance programs; eligibility criteria apply.

Please see full Important Safety Information throughout and click here for full Prescribing Information.

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

TRAKAssist™
Access. Resources. Support.

ORDER

Ordering

VITRAKVI® (larotrectinib) is available from:

Specialty Pharmacy		
Accredo	Phone: 1-855-540-1797 Fax: 1-877-327-7120 www.accredo.com	Mon-Fri 8:30 AM–9:00 PM EST
CVS Specialty	Phone: 1-800-790-1698 Fax: 1-855-296-0210 www.cvsspecialty.com	Mon-Fri 7:30 AM–8:30 PM EST
US Bioservices	Phone: 1-833-230-1407 Fax: 1-833-878-5917 www.usbioservices.com	Mon-Fri 8:00 AM–8:00 PM EST

Specialty Distributor		
Amerisource Bergen Healthcare (ASD)	Phone: 1-800-746-6273 Fax: 1-800-547-9413 www.asdhealthcare.com	Mon-Thurs 7:00 AM–6:30 PM CST Fri 7:00 AM–6:00 PM CST

Important Safety Information (cont'd)

Neurotoxicity (cont'd): 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.

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:
NDC: 50419-390-01

100-mg capsules:
NDC: 50419-391-01

20-mg/mL oral solution:
NDC: 50419-392-01

NDC=National Drug Code.

Important Safety Information (cont'd)

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.

Please see full Important Safety Information throughout and click here for full Prescribing Information.

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

TRAKAssist™
Access. Resources. Support.

The VITRAKVI Commitment Program™ is available to patients taking VITRAKVI®

The VITRAKVI Commitment Program™ ensures that *NTRK* gene fusion positive patients will pay for VITRAKVI only if they receive a clinical benefit* from VITRAKVI. Full or partial refunds (for 60 days) will be issued to patients and the primary PBM/Payer when lack of a clinical benefit occurs (program rules apply).

Eligibility Criteria for the VITRAKVI Commitment Program™:

- Patients who are enrolled in commercial insurance plans, Medicare Part D, Medicaid, other government insurance, or who are responsible for 100% of the cost of VITRAKVI
- Healthcare provider (HCP) must provide the Specialty Pharmacy with the patient's lab test result confirming a positive test for *NTRK* gene fusion using RT-PCR, FISH, or NGS testing methodology
- Patient must receive product via a VITRAKVI In-Network Specialty Pharmacy ("SP")
  - Accredo, CVS Specialty, or US Bioservices
- Patient does not receive clinical benefit within 90 days of treatment initiation on VITRAKVI
- SP will monitor and determine whether a patient meets the above eligibility criteria ("Eligible Patient"). If eligible, the SP will send an attestation to the HCP
- HCP must complete and submit the attestation form to the SP for patients who stop taking VITRAKVI within 90 days of treatment initiation
  - HCP must submit completed attestation form within 120 days of last prescription fulfilled within the VITRAKVI Commitment Program™ eligibility period

Patient Selection

Select patients for treatment with VITRAKVI based on the presence of an *NTRK* gene fusion in tumor specimens. An FDA-approved test for the detection of *NTRK* gene fusion is not currently available.

*Clinical benefit is defined at the discretion of the physician, and does not require any confirmatory documentation by the physician. Discontinuation solely due to adverse events does not qualify patients for the VITRAKVI Commitment Program™.

Reference: VITRAKVI [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; July 2019.

Please see full Important Safety Information throughout and click here for full Prescribing Information.

Important Safety Information (cont'd)

Hepatotoxicity (cont'd): 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.

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

Your first step:
Contact

TRAK Assist™
Access. Resources. Support.

Get information on VITRAKVI® (larotrectinib) and TRAK Assist™ 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
- ☑ Testing locations for NGS for *NTRK* gene fusions
- ☑ 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

Please see full Important Safety Information throughout and click here for full Prescribing Information.

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

BAYER