TRAK Assist™
Access. Resources. Support.

Instructions for completing the VITRAKVI® (larotrectinib) patient support service request form and prescription

Please complete the following steps to enroll your patients in TRAK Assist™ for VITRAKVI.

1 PHYSICIAN

- Complete steps 1-6 on pages 2 and 3
- Sign and date form on page 3
- Missing information and illegible forms may cause delays

2 PATIENT

- Read Patient Authorization on page 4
- Sign and date form on Page 4
- Missing signatures will cause a delay

3 OFFICE

- Prescriber faxes the form, along with the copies of the patient's pharmacy insurance card(s) (front and back), to **1-888-506-TRAK** (1-888-506-8725)

For more information please call **1-844-634-TRAK** (1-844-634-8725).

Please see Indication and full Important Safety Information on page 6 and full Prescribing Information.

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

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***Required fields.**

STEP 1: PATIENT INFORMATION

Patient name* _____ DOB* _____ (MM/DD/YYYY) ○ Male ○ Female

Address* _____ City* _____ State* _____ Zip* _____

Home phone _____ Cell phone _____ OK to leave a detailed message about VITRAKVI ○ Yes ○ No

Email _____ Preferred language _____

Primary caregiver _____ Preferred contact method _____

STEP 2: PATIENT INSURANCE INFORMATION ○ No Insurance

Please fax a copy of the patient's insurance card(s) (front and back) along with this form. Please complete section below or include a copy of the patient's pharmacy benefits.

PRESCRIPTION DRUG INSURANCE

Prescription drug insurer* _____ Phone _____ Policy ID* _____

Card holder name _____ Relationship to card holder _____

Group number _____ BIN number _____ PCN number _____

PRIMARY INSURANCE

Primary insurance carrier* _____ Phone _____ Policy ID* _____

Card holder name _____ Relationship to card holder _____ Group number _____

SECONDARY INSURANCE

Secondary insurance carrier* _____ Phone _____ Policy ID* _____

Card holder name _____ Relationship to card holder _____ Group number _____

If prescription insurance information is not available, provide medical insurance information.

STEP 3: PRESCRIBER INFORMATION ○ In-office Dispensing

Prescriber name* _____ Tax ID _____ NPI _____

Name of supervising/collaborating physician (if applicable) _____

Street address* _____ City* _____ State* _____ Zip* _____

Office contact _____ Phone* _____

Fax* _____ Email _____

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Name of patient* _____ DOB* _____ MM/DD/YYYY

STEP 4: DIAGNOSTICS INFORMATION

Has the patient tested positive for *NTRK* gene fusion?

◯ **Yes.** Please include copy of results or provide lab name and lab test date.

Lab name _____ Lab test date _____

Select Test Type

◯ Next-Generation Sequencing (NGS) ◯ Fluorescence in situ hybridization (FISH) ◯ Immunohistochemistry (IHC)† ◯ Polymerase chain reaction (PCR)

◯ **No.** Is assistance needed to find an appropriate lab? ◯ Yes ◯ No

†Following a positive TRK IHC test, confirmation of *NTRK* gene fusion is needed prior to initiation of VITRAKVI treatment.

STEP 5: PRESCRIPTION INFORMATION

Must be *NTRK* gene fusion positive.

ICD-10 Diagnosis Code(s) _____ **Dosage Form*** VITRAKVI in: ◯ 25-mg capsule ◯ 100-mg capsule ◯ 20-mg/mL 100 mL bottle oral solution

◯ **SIG*** _____ **Quantity/Supply*** _____ **Refills** _____

Home Healthcare Visits for Oral Solution (physician please select an option):

◯ Home healthcare nurse visit (During the home visit, the home healthcare nurse will educate patient/caregiver on insertion of adapter and use of syringes for medication withdrawal)

◯ Patient/caregiver will be seen in this physician's office for education on insertion of adapter and use of syringes for medication withdrawal

Preferred Pharmacy (not guaranteed): ◯ Accredo – **Phone:** 1-855-540-1797 **Fax:** 1-877-327-7120

◯ CVS Specialty – **Phone:** 1-800-790-1698 **Fax:** 1-855-296-0210

◯ US Bioservices – **Phone:** 1-833-230-1407 **Fax:** 1-833-878-5917

Allergies _____ Other medications taken _____

I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge.
I appoint TRAK Assist™, on my behalf, to convey this prescription to the dispensing pharmacy. I understand that I may not delegate signature authority.

STEP 6: PRESCRIBER SIGNATURE

SIGN, DATE, and FAX to 1-888-506-TRAK

Dispense as written* _____ Date* _____
Prescriber signature

Substitutions permitted* _____ Date* _____
Prescriber signature

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***Required fields.**

Name of patient* _____ DOB* _____ MM/DD/YYYY

PATIENT AUTHORIZATION

I authorize the use and disclosure of my Protected Health Information ("PHI") as defined by the Health Insurance Portability and Accountability Act of 1996, which was amended by the Health Information Technology for Economic and Clinical Health Act (as amended, "HIPAA"). I understand that Protected Health Information is health information that identifies me or that could reasonably be used to identify me and that this authorization to release my information is voluntary.

I authorize my healthcare provider, including my physician, pharmacies, other healthcare providers, and my health plan, to disclose my name, address, and telephone number along with certain medical information including my treatment, my eligibility for assistance, the coordination of my treatment, the receipt of my medication and my participation in the Patient Support Program, TRAK Assist, and the Vitrakvi Commitment Program, to Bayer and its agents (including Oncology Group Purchasing Organizations and facilities where I receive treatment).

I allow the use and disclosure of my PHI for the following purposes: (1) To verify my insurance information; (2) to ensure the accuracy and completeness of the TRAK Assist enrollment form; (3) to help with my reimbursement questions; (4) to determine if I qualify for patient assistance; (5) to determine my eligibility for other sources of funding; (6) to provide education, training, and ongoing support on the use of my medication; (7) to send me information on related products and services related to my treatment; (8) to send me refill reminders for my prescription and to encourage appropriate use; (9) to communicate with me, my healthcare providers and health plan insurers about my medical care and treatment; (10) to contact me for market research feedback; (11) for sales support purposes and (12) to comply with applicable law.

This authorization shall be in effect for 5 years from the date of my signature, or the date of last enrollment, whichever comes first, unless a shorter period is required by law. If I (or my representative) revoke this authorization, healthcare providers will stop using my PHI for the purposes outlined in this authorization, but the revocation will not affect prior use or disclosure of my PHI in reliance on this authorization. I (or my representative) may revoke this authorization at any time by calling 1-844-634-8725 or writing to: TRAK Assist, PO Box 220765, Charlotte, NC 28222-0765.

I also understand that, under this authorization, entities that receive my PHI may not be required by law to keep the information private and it will no longer be protected by the privacy law. It may become available in the public domain.

I understand that I do not need to sign this form to receive medical treatment or medication. I (or my representative) have read and understand the terms of this authorization form, and have had an opportunity to ask questions about the uses and disclosures of PHI described above. All of my questions have been answered to my satisfaction. I authorize the use and disclosure of my information as described in this form.

I (or my representative) have the right to receive a copy of this authorization upon request. I understand that my healthcare providers, insurers, and health plans may receive remuneration (payment) from Bayer in exchange for disclosing my PHI to Bayer.

I agree to the TRAK Assist $0 Co-Pay Program terms and conditions on page 5.

Patient or Patient Representative Signature* **SIGN and DATE**

_____

Name of Patient Representative*

_____

Relation to Patient*†

_____

†If signed by the Patient's Representative, a description of the representative's relationship to the Patient and such person's authority to act for the Patient must be provided in the space above.

(Cont'd on next page)

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***Required fields.**

Name of patient* _____ DOB* _____
MM/DD/YYYY

PATIENT AUTHORIZATION

TRAK Assist $0 Co-Pay Program Terms & Conditions

- Patient must meet eligibility requirements of the TRAK Assist $0 Co-Pay Program; for example, only commercially insured patients are eligible
- Patient must inform TRAK Assist $0 Co-Pay Program of change in insurance status
- It is required that the patient understand, accept and meet the terms of all the TRAK Assist $0 Co-Pay Program requirements
- Use of the TRAK Assist $0 Co-Pay Program must be consistent with and not prohibited by the requirements of the patient's health insurance
- The TRAK Assist $0 Co-Pay Program benefit has a max amount of $25,000 per year, per patient
- The Trak Assist $0 Co-Pay Program is for commercially insured patients using VITRAKVI® for an approved FDA indication
- The Trak Assist $0 Co-Pay Program does not cover costs for changes associated with administering VITRAKVI® or patient visits
- Offer valid only for patients treated in the USA, including Puerto Rico, Guam and US Territories
- Bayer reserves the right to determine eligibility, monitor participation, fairly distribute product and may change or end the TRAK Assist $0 Co-Pay Program at any time with or without notice
- Patient agrees to provide necessary health information to the administration of the TRAK Assist $0 Co-Pay Program
- For questions about the TRAK Assist $0 Co-Pay Program, please call us at 1-844-634-8725

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

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 see full Prescribing Information.

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