Helping Your Patients Get Their Bayer Medications Through Access Services by Bayer™

Instructions for completing the Access Services by Bayer Patient Support Request Form (SRF).

SELECT ALL THAT APPLY:

Benefits Investigation* *(complete steps 1-3)*

- **Check patient's insurance** to determine coverage
- **Eligible** patients auto-enrolled in the $0 Co-pay Program

Access Services by Bayer™ | VITRAKVI® (larotrectinib) | BAYER

PATIENT SUPPORT REQUEST FORM

PATIENT CHOOSES TO OPT-IN TO* ○ Benefits Investigation† ○ $0 Co-pay Program (for commercially insured)

Phone: 1.800.288.8374
Fax: 1.800.390.1826

COMPLETE ALL REQUIRED FIELDS INCLUDING PATIENT SIGNATURES TO AVOID DELAYS IN TREATMENT

STEP 1 Patient Information

○ *I consent to receive text messages relating to Access Services by Bayer prescriptions and healthcare to the cell phone number provided. Consent may be revoked at any time and is not a condition of services. To opt-out, text STOP. Message and data rates may apply.*

Required fields (*)

Last Name*:	First Name*:	Date of Birth*:	Gender: ○ M ○ F
Street*:	City*:	State*:	ZIP*:
Home Phone: ( )	Cell: ( )	OK to Leave a Detailed Message? ○ Yes ○ No	
Email:	Preferred Language:	Preferred contact method:	
Alternate Contact's First and Last Name:	Relationship:	Alternate Contact's Phone: ( )	

Alternate contacts may include family members to whom the patient has given permission to speak with Access Services by Bayer™ on their behalf

STEP 2 Patient Insurance Information (send in copy of insurance cards)

○ **No Insurance**

Check this circle if the patient does not have health insurance

Patient's Medical Insurance*:			Telephone: ( )
Group Number:	BIN:	PCN:	Policy ID Number*:
Subscriber Name:		Date of Birth:	Relationship to card holder:
Patient's Pharmacy Insurance*:			Telephone: ( )
Group Number:	BIN:	PCN:	Policy ID Number*:
Subscriber Name:		Date of Birth:	Relationship to card holder:
Patient's Secondary Insurance*:			Telephone: ( )
Group Number:	BIN:	PCN:	Policy ID Number*:
Subscriber Name:		Date of Birth:	Relationship to card holder:

STEP 3 Prescriber Information

Site/Facility Name:	Prescriber Name*:		
Street*:	City*:	State*:	ZIP*:
Telephone*: ( )	Fax*: ( )		
Office Contact Name:	Email:	Telephone: ( )	
Tax ID #:	NPI #:		

STEP 4 Diagnostics Information

Has the patient tested positive for *NTRK* gene fusion?
○ **Yes** ○ **No** If yes, please provide lab test date:

If yes, please select test type:
○ Next-Generation Sequencing (NGS) ○ Fluorescence in situ hybridization (FISH)
○ Immunohistochemistry (IHC)‡ ○ Polymerase chain reaction (PCR)

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

Prescribers in NY must submit prescriptions on official state prescription blanks with this form. Signature must be from prescriber stated in Step 3

STEP 5 Prescription Information

Prescribers in the state of New York: Please submit prescriptions on official state prescription blanks in conjunction with this form.

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 ○ 20-mg/mL 2x 50 mL oral solution

SIG* **Quantity*:** **Refills:**

Known allergies: Other medications:

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

PRESCRIBER SIGN, DATE, AND FAX TO 1.800.390.1826

Prescriber signature (required)*: **Date*:** / /

Missing signatures **WILL** cause a delay in processing

To report any adverse events, product technical complaints, or medication errors associated with the use of Vitrakvi, contact: Bayer at 1-888-842-2937, or send the information to DrugSafety.GPV.US@bayer.com.
Please see Indication and full Important Safety Information on page 3, and click here for full Prescribing Information.
*Results of Benefit Investigation are not a guarantee of coverage and should be verified by dispensing provider.

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BAYER

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Group Number:	BIN:	PCN:	Policy ID Number*:
Subscriber Name:		Date of Birth:	Relationship to card holder:
Patient's Pharmacy Insurance*:			Telephone: ( )
Group Number:	BIN:	PCN:	Policy ID Number*:
Subscriber Name:		Date of Birth:	Relationship to card holder:
Patient's Secondary Insurance*:			Telephone: ( )
Group Number:	BIN:	PCN:	Policy ID Number*:
Subscriber Name:		Date of Birth:	Relationship to card holder:

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BAYER

PATIENT HIPAA AUTHORIZATION

I voluntarily provide this authorization for the use and disclosure of my Protected Health Information ("PHI"), as such term is defined by the Health Insurance Portability and Accountability Act of 1996 (as amended, "HIPAA"). I understand that PHI is health information that identifies me or that could reasonably be used to identify me.

I authorize my healthcare provider, including my physician and pharmacy, and my health plan, to disclose to Bayer and its contracted agents my name, address, telephone number, health insurance status and coverage and such medical information as may be necessary for me to enroll in Access Services by Bayer™. I understand this disclosure(s) will contain PHI, including information about my current medical condition, treatment, coordination of treatment and receipt of medication. I allow the use and disclosure of my PHI to Bayer its contracted agents for the following purposes:

- To verify my insurance information and coverage
- To ensure the accuracy and completeness of the Access Services by Bayer™ Enrollment Form
- To help with my insurance coverage questions for Bayer medications
- To determine if I qualify for other Bayer patient support programs
- To determine my eligibility for other sources of prescription medication financial assistance
- To provide education, training, and ongoing support on the use of my Bayer medication
- To send me information on Bayer products and services related to my treatment
- To send me refill reminders for my Bayer prescription medication and to encourage its appropriate use
- To communicate with me, my healthcare providers and health plan about my medical care and treatment
- To contact me for market research feedback, sales support purposes, and as necessary to comply with applicable laws
- Bayer may contact me for potential adverse event follow-up information

I understand that:

- This Authorization will remain in effect until the end of my participation in Access Services by Bayer™ or 5 years, unless subject to applicable law from the date of my signature on this Authorization, whichever occurs later.
- I may cancel this Authorization at any time by writing to: **Access Services by Bayer, PO BOX 2230, Columbus OH 43216**.
- If I cancel this Authorization my healthcare provider and health plan will stop sharing my PHI with Bayer and its contracted agents. However, the revocation will not affect prior use or disclosure of my PHI in reliance on this Authorization.
- I may opt-out of being contacted for market research feedback, sales support purposes and still enroll in the patient support program.
- That entities that receive my PHI in accordance with this Authorization may not be required by law to keep the information private and that it will no longer be protected by the HIPAA privacy law. It may become available in the public domain.
- I do not need to sign this Authorization to receive (i) medical treatment or medication or (ii) coverage, payment, enrollment in or eligibility for benefits from my health plan. However, if I do not sign this Authorization, I may not participate in Access Services by Bayer™ or be eligible for other Bayer patient support programs.
- I understand that some of my health care providers, such as my pharmacies, may receive payment from Bayer in return for services that require use or disclosure of my PHI to Bayer and its contracted agents.

I have read and understand the terms of this Authorization and have had an opportunity to ask questions about the uses and disclosures of PHI. I understand that I am entitled to receive a signed copy of this Authorization and I can also get a copy by contacting Access Services by Bayer™ at 1-800-288-8374.

PATIENT SIGN AND DATE

Patient name (print)*:

Patient (or legal guardian) signature*: **Date*:** / /

If signed by a legal representative: Print Name:

Relationship to patient:

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$0 CO-PAY PROGRAM FOR VITRAKVI TERMS & CONDITIONS

- Patient must meet eligibility requirements of the $0 Co-pay Program for VITRAKVI; for example, only **commercially insured patients are eligible**
- Patient must inform $0 Co-pay Program for VITRAKVI of change in insurance status
- It is required that the patient understand, accept and meet the terms of all the $0 Co-pay Program for VITRAKVI requirements
- Use of the $0 Co-pay Program for VITRAKVI must be consistent with and not prohibited by the requirements of the patient's health insurance
- The $0 Co-pay Program for VITRAKVI benefit has a max amount of $25,000 per year, per patient
- The $0 Co-pay Program for VITRAKVI is for commercially insured patients using VITRAKVI® for an approved FDA indication
- The $0 Co-pay Program for VITRAKVI 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 $0 Co-pay Program for VITRAKVI at any time with or without notice
- Patient agrees to provide necessary health information to the administration of the $0 Co-pay Program for VITRAKVI
- For questions about the $0 Co-pay Program for VITRAKVI, please call us at 1-647-245-5637

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 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.
- **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.

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