

Vitrakvi
Commitment Program[™]



Bayer is committed to offering comprehensive access, reimbursement support and patient assistance services to patients in need. The Vitrakvi Commitment Program[™] ensures that *NTRK* gene fusion positive patients will pay for Vitrakvi only if they receive a clinical benefit* from Vitrakvi.

Bayer's Vitrakvi Commitment Program[™] will refund the cost of up to 60 days' supply of Vitrakvi to payers, patients and third-party organizations paying on behalf of patients, in the event eligible patients do not experience a clinical benefit.*

+ A limit of 23% is set to conform with the Medicaid Program's guidance for Best Price and Medicaid Rebate calculations. The Average Manufacturer Price (AMP) is defined by law and calculated according to regulatory guidance. The co-pay amount may be deducted from the refund to be provided to the payer.

Who is Eligible for the Vitrakvi Commitment Program[™] ?

Patients who have:



A positive *NTRK* gene fusion diagnostic test (next-generation sequencing, fluorescence *in situ* hybridization or polymerase chain reaction) prior to treatment initiation with Vitrakvi



Filled their prescriptions at one of the designated Vitrakvi In-Network Specialty Pharmacies (Accredo, CVS Specialty or US Bioservices)



Not experienced a clinical benefit* within the first 90 days after initiating treatment

Patients will be fully refunded for their cost of Vitrakvi. Commercial, Medicare, Medicaid, other government insurance and cash paying patients qualify.

How Does the Vitrakvi Commitment Program[™] Work?



Participating Network Specialty Pharmacies will contact the prescribing physician regarding any patients that discontinue Vitrakvi to determine the reason for discontinuation of therapy, within the first 90 days of treatment



Healthcare Provider must provide Specialty Pharmacy with the patient's lab test result confirming a positive *NTRK* gene fusion diagnostic test

Healthcare Provider must complete and submit the attestation form for patients who stop taking Vitrakvi within 90 days of treatment initiation after not experiencing a clinical benefit**



Working with its Network of Specialty Pharmacies, Bayer will issue refunds to patients and payers for up to 60 days of Vitrakvi claims attributable to patients who did not experience a clinical benefit while on therapy

+Healthcare Provider must submit completed attestation form within 120 days of last prescription fulfilled within the Vitrakvi Commitment Program[™] eligibility period

*Clinical benefit (i.e., partial response, complete response or stable disease) 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[™].

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.¹

Important Safety Information for Vitrakvi[®] (larotrectinib)

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 neurological 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%).

Please see additional Important Safety Information throughout and the full Prescribing Information.

How do Patients get Reimbursed?



- // Bayer will refund the cost of the co-payment or co-insurance for the first 60 treatment days of Vitrakvi to the patient or to someone who has made a payment in the patient's name
- // Refunds to patients will be made by the Vitrakvi In-Network Specialty Pharmacy in the quarter after discontinuation of therapy
- // The Vitrakvi In-Network Specialty Pharmacy will coordinate individually with patients regarding the processing of refund payments

How do Payers and Third-Party Organizations get Reimbursed?



- // **Commercial Payers**
Bayer will pay refunds to commercial payers annually in the form of a rebate. The rebate will be equal to the WAC value of Vitrakvi dispensed to patients eligible for refunds (following discontinuation of therapy and receipt of a signed attestation form from the patient's doctor) – less the actual patient copays⁺
- // **Medicare Part D and Fee-for-Service Medicaid**
The dispensing Specialty Pharmacy will pay refunds to government payers in the calendar quarter following discontinuation of therapy and receipt of a signed attestation form
- // The refunds to payers will not be conditional on any performance by the payer and no contract will be required between the payer and Bayer
- // Any third-party charitable organization that paid copay/coinsurance on behalf of a patient will also be eligible to receive reimbursement of payments after discontinuation of therapy and receipt of a signed attestation form

⁺The limit of 23% is set to conform with the Medicaid Program's guidance for Best Price and Medicaid Rebate calculations. The Average Manufacturer Price (AMP) is defined by law and calculated according to regulatory guidance. The co-pay amount may be deducted from the refund to be provided to the payer.

Important Safety Information for Vitrakvi® (larotrectinib) (continued)

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.

Please see additional Important Safety Information throughout and the full Prescribing Information.

What is the TRAK Assist[™] Program?



TRAK Assist[™] is a patient support program offered by Bayer that provides patients taking Vitrakvi with comprehensive access, reimbursement support and patient assistance services such as:



A dedicated phone line providing patients with a direct nurse or pharmacist - 1-844-634-TRAK (8725)



Information on testing locations for next-generation sequencing for *NTRK* gene fusions



Resources for diagnostic testing



Insurance benefits information

For more information on this program and eligibility requirements, please visit:
http://labeling.bayerhealthcare.com/html/products/pi/vitrakvi_PI.pdf

Vitrakvi was developed by Bayer and Loxo Oncology, Inc.
Bayer reserves the right to modify or discontinue the TRAK Assist or Vitrakvi Commitment Program at any time.

Important Safety Information for Vitrakvi[®] (larotrectinib) (continued)

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.

References:

1. Vitrakvi[®](larotrectinib) capsules and solution for oral use [Prescribing Information]. Stamford, CT: Loxo Oncology Inc.; November 2018.