Larotrectinib (VITRAKVI)
Criteria for Use
June 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTERnet* or *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive larotrectinib.

- ☐ Malabsorption syndrome or other condition affecting oral absorption
- ☐ Unmanageable drug interaction
- ☐ Known pregnancy
- ☐ Lactating

Inclusion Criteria

The answers to ALL must be fulfilled to meet criteria.

- ☐ Patient has a metastatic solid tumor that is unresectable with an NTRK gene fusion without a known acquired resistance mutation (G595R, G623R, G696A, and F617L)
- ☐ Patient has progression on standard treatment(s) or no standard alternative treatment exists
- ☐ Baseline hepatic function (AST, ALT, Tbili) evaluated for larotrectinib dose adjustment

Additional Inclusion Criteria

The answer to the following must be fulfilled to meet criteria.

- ☐ Care is provided by a VA/VA Community Care oncology provider
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented.
- ☐ Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2

Additional Inclusion Criteria, *if applicable*

- ☐ For female patients who can become pregnant: Pregnancy must be excluded prior to receiving Larotrectinib.
- ☐ For females who can become pregnant and males with partners who can become pregnant: Counseling provided on potential risks vs. benefits of treatment and the use of effective contraception during therapy and for at least 1 week after the final dose.

Other Justification

- ☐ _____

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