MEDICAL MUTUAL®

Drug Policy

Policy:	Vitrakvi (larotrectinib)	Annual Review Date: 12/19/2024 Last Revised Date: 12/19/2024

OVERVIEW

Vitrakvi, a kinase inhibitor, 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.

POLICY STATEMENT

This policy involves the use of Vitrakvi. Prior authorization is recommended for pharmacy benefit coverage of Vitrakvi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Vitrakvi as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Vitrakvi be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vitrakvi is recommended in those who meet the following criteria:

1. <u>Solid Tumors</u>

Criteria. *Patient must meet the following criteria*

- **A.** The member has a solid tumor that is metastatic or surgical resection is likely to result in severe morbidity; AND
- **B.** The member does NOT have a known acquired resistance mutation [documentation required]; AND
- **C.** There are no satisfactory alternative treatments or the patient has progressed following treatment; AND
- **D.** Tumors are neurotrophic receptor tyrosine kinase (NRTK) gene fusion positive, as detected by an FDA-approved diagnostic test [documentation required]; AND
- **E.** The member has fully recovered from toxic effects of prior chemotherapy; AND
- **F.** The member has a Karnofsky score greater than 50% or an ECOG score of 2 or less; AND
- **G.** Vitrakvi is prescribed by or in consultation with a hematologist or oncologist

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 90 days (3 months)
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Vitrakvi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Vitrakvi® capsules and oral solution [prescribing information]. Stamford, CT: Loxo Oncology, Inc.; November 2023.
2. Larotrectinib. In: DRUGDEX [online database]. Truven Health Analytic; Greenwood Village, CO. Last updated 2 December 2024. Accessed on 23 December 2024.
3. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 19 December 2023.
4. Larotrectinib. In: Lexi-Drugs. Lexicomp. Wolters Kluwer Clinical Drug Information, Inc.; Riverwoods, IL. Available at: http://www.online.lexi.com. Last updated 5 December 2023. Accessed on 19 December 2023.