

Vitrakvi (larotrectinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Vitrakvi (larotrectinib) 100 mg	2 capsules per day
Vitrakvi (larotrectinib) 25 mg	6 capsules per day
Vitrakvi (larotrectinib) 20 mg/mL solution	10 mL per day

May approve up to 4 capsules of the 100 mg capsule or 20 mL per day of the 20 mg/mL solution to allow for coadministration of a strong or moderate CYP3A4 inducer.

APPROVAL CRITERIA

Requests for Vitrakvi (larotrectinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis for a solid tumor; **AND**
- II. Individual is using as monotherapy (NCCN 2A); **AND**
- III. Individual's tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation; **AND**
- IV. Individual's tumor is metastatic or where surgical resection is likely to result in severe morbidity; **AND**
- V. Individual has no satisfactory alternative treatments or has progressed following treatment; **AND**
- VI. Individual has not received treatment with another NTRK inhibitor (for example, entrectinib);

OR

- VII. Individual has a diagnosis of Pediatric Diffuse High-Grade Glioma (NCCN 2A); **AND**
- VIII. Individual has TRK-fusion positive mutation;

AND

- IX. If requesting Vitrakvi oral solution, individual is unable to swallow the oral capsule dose form due to a clinical condition, including, but not limited to the following:
 - A. Dysphagia; **OR**
 - B. Individual's age.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 10, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 10, 2024.
 - a. Ampullary Adenocarcinoma. V2.2024. Revised August 02, 2024.
 - b. Biliary Tract Cancers. V4.2024. Revised August 29, 2024.
 - c. Breast Cancer. V4.2024. Revised July 3, 2024.
 - d. Central Nervous System Cancers. V3.2024. Revised September 30, 2024.
 - e. Cervical Cancer. V4.2024. Revised September 24, 2024.
 - f. Colon Cancer. V5.2024. Revised August 22, 2024.
 - g. Esophageal and Esophagogastric Junction Cancers. V4.2024. Revised July 30, 2024.
 - h. Gastric Cancer. V4.2024. Revised August 12, 2024.
 - i. Gastrointestinal Stromal Tumors. V2.2024. Revised July 31, 2024.
 - j. Head and Neck Cancers. V4. 2024. Revised May 1, 2024.
 - k. Hepatocellular Carcinoma. V3.2024. Revised September 24, 2024.
 - l. Histiocytic Neoplasms. V2.2024. Revised July 19, 2024.
 - m. Cutaneous Melanoma. V3.2024. Revised September 23, 2024.
 - n. Neuroendocrine and Adrenal Tumors. V2.2024. Revised August 1, 2024.
 - o. Non-Small Cell Lung Cancer. V10.2024. Revised September 23, 2024.
 - p. Occult Primary. V2.2025. September 11, 2024.
 - q. Ovarian Cancer. V3.2024. Revised July 15, 2024.
 - r. Pancreatic Cancer. V3.2024. Revised August 02, 2024.
 - s. Pediatric Central Nervous System Cancers. V1.2024. Revised February 26, 2024.
 - t. Rectal Cancer. V4.2024. Revised August 22, 2024.
 - u. Small Bowel Adenocarcinoma. V5.2024. Revised September 13, 2024.
 - v. Soft Tissue Sarcoma. V3.2024. Revised September 27, 2024.
 - w. Thyroid Carcinoma. V4.2024. Revised August 19, 2024.
 - x. Uterine Neoplasms. V3.2024. Revised September 20, 2024.
 - y. Vaginal Cancer. V2.2025. Revised August 8, 2024.
 - z. Vulvar Cancer V4.2024. Revised May 1, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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