

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Vitrakvi Prior Authorization Policy

- Vitrakvi® (larotrectinib capsules and oral solution – Bayer)

REVIEW DATE: 02/07/2024

OVERVIEW

Vitrakvi, a kinase inhibitor, is indicated for the treatment of **solid tumors** in adult and pediatric patients 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

Guidelines

The National Comprehensive Cancer Network (NCCN) Compendium notes Vitrakvi as an option for the treatment of the following cancers with *NTRK* gene fusion-positive tumors as category 2A recommendations: ampullary adenocarcinoma, breast cancer, central nervous system cancers, cervical cancer, cholangiocarcinoma (intrahepatic and extrahepatic), colon cancer, cutaneous melanoma, endometrial carcinoma, epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer, Erdheim-Chester disease, esophageal and esophagogastric cancer, gallbladder cancer, gastric cancer, gastrointestinal stromal tumors, hepatocellular carcinoma, Langerhans Cell histiocytosis, neuroendocrine and adrenal tumors, non-small cell lung cancer, occult primary, pancreatic cancer, rectal cancer, Rosai-Dorfman disease, salivary gland tumors, small bowel adenocarcinoma, soft tissue sarcoma, thyroid carcinoma, uterine sarcoma, and vulvar cancer.²

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vitrakvi. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. Solid Tumors. Approve for 1 year if the patient meets the following (A and B):

Note: Examples of solid tumors include breast cancer, colon cancer, hepatobiliary cancer, histiocytic neoplasm, ovarian cancer, pancreatic cancer, salivary gland tumors, thyroid cancer, and rectal cancer.

A) The tumor is positive for neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion; **AND**

B) Patient meets one of the following (i or ii):

i. The tumor is metastatic; **OR**

ii. Surgical resection of tumor will likely result in severe morbidity.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vitrakvi is not recommended in the following situations:

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

REFERENCES

1. Vitrakvi® capsules and oral solution [prescribing information]. Whippany, NJ: Bayer; November 2023.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed February 4, 2024. Search terms: larotrectinib.