



Prior Authorization Oncology – Vitrakvi® (larotrectinib capsules and oral solution)

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Product Identifier(s)

62092

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National Formulary Medical Necessity

Cigna covers larotrectinib (Vitrakvi®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

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

FDA Indication(s)

1. **Solid Tumors.** Approve for 3 years if the individual meets the following criteria (A, B, and C):
 - A) The individual's tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation; **AND**
 - B) The individual meets one of the following criteria (i or ii):
 - i. The tumor is metastatic; **OR**
 - ii. Surgical resection of tumor will likely result in severe morbidity; **AND**
 - C) The individual meets one of the following criteria (i or ii):
 - i. There are no satisfactory alternative treatments; **OR**

- ii. The individual has disease progression following treatment.

Conditions Not Covered

Larotrectinib (Vitrakvi®) is considered experimental, investigational or unproven for ANY other use.

Background

Overview

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

Guidelines

The National Comprehensive Cancer Network (NCCN) Compendium lists the following cancers as recommended uses for Vitrakvi for patients with NTRK gene fusion-positive tumors: 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, non-small cell lung cancer, ovarian cancer, pancreatic cancer, rectal cancer, Rosai-Dorfman disease, salivary gland tumors, small bowel adenocarcinoma, soft tissue sarcoma, thyroid carcinoma, uterine sarcoma, and vulvar cancer.²

References

1. Vitrakvi® capsules and oral solution [prescribing information]. Whippany, NJ: Bayer; March 2021.
2. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed January 23, 2022. Search terms: larotrectinib.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	01/26/2022

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