PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Vitrakvi Prior Authorization Policy
- Vitrakvi® (larotrectinib capsules and oral solution – Bayer)

REVIEW DATE: 02/07/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

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

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

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

is(are) considered experimental, investigational, or unproven for ANY other use(s).

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria change.	01/25/2023
Annual Revision	No criteria change.	02/07/2024