PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Neurotrophic Tyrosine Receptor Kinase Gene Fusion) – Vitrakvi Prior Authorization Policy
- Vitrakvi® (larotrectinib capsules and oral solution – Bayer)

REVIEW DATE: 02/18/2026

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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

Vitrakvi is addressed in the National Comprehensive Cancer Network (NCCN) guidelines for the following:

- **Solid Tumors:** 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, head and neck cancer, hepatocellular carcinoma, Langerhans Cell histiocytosis, neuroendocrine and adrenal tumors, non-small cell lung cancer, ovarian/endometrial/serous carcinoma, occult primary, pancreatic cancer, pediatric diffuse high-grade gliomas, rectal cancer, Rosai-Dorfman disease, salivary gland tumors, small bowel adenocarcinoma, soft tissue sarcoma, thyroid carcinoma, uterine sarcoma, and vulvar cancer.[2]

- **Pediatric Central Nervous System Cancers:** Guidelines (version 1.2026 – November 25, 2025) recommend Vitrakvi for *NTRK* fusion-positive disease in the adjuvant setting or for recurrent or progressive disease (both category 2A).[3] The guideline refers to children and adolescents ≤ 21 years of age.

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 BOTH of 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.

Other Uses with Supportive Evidence

2. **Pediatric Diffuse High-Grade Gliomas.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≤ 21 years of age; AND
   B) The tumor is positive for neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion; AND
   C) Patient meets ONE of the following (i or ii):
      i. The medication is used as adjuvant therapy; OR

ii. The medication is used for recurrent or progressive disease.

CONDITIONS NOT COVERED

- **Vitrakvi® (larotrectinib capsules and oral solution - Bayer) is(are) considered experimental, investigational or unproven for ANY other use(s); 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. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 16, 2026. Search terms: larotrectinib.
3. The NCCN Pediatric Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2026 – November 25, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 16, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/25/2023
Annual Revision	No criteria changes.	02/07/2024
Annual Revision	**Pediatric Diffuse High-Grade Gliomas:** Added new approval condition and criteria under "Other Uses with Supportive Evidence" based on guideline recommendations.	02/26/2025
Annual Revision	No criteria changes.	02/18/2026