PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 12/16/2020

OVERVIEW
Vitrakvi, a kinase inhibitor, is indicated for the treatment of adult and pediatric patients with **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/Compendium
The National Comprehensive Cancer Network (NCCN) Compendium lists the following cancers as recommended uses for Vitrakvi:[2] breast cancer, cervical cancer, esophageal and esophagogastric cancer, gastric cancer, gastrointestinal stromal tumors (GISTs), extra and intrahepatic cholangiocarcinoma, gallbladder cancer, hepatocellular carcinoma, soft tissue sarcoma, uterine sarcoma, endometrial carcinoma, small bowel adenocarcinoma, angiosarcoma, rhabdomyosarcoma, retroperitoneal/intra-abdominal sarcoma, salivary gland tumors, cutaneous melanoma, central nervous system cancers, thyroid carcinoma, rectal cancer, non-small cell lung cancer, colon cancer, ovarian cancer, pancreatic cancer, and vulvar cancer (squamous cell carcinoma).

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 Indications

1. **Solid Tumors.** Approve for 3 years if the patient meets the following criteria (A, B, and C):
   - **A)** Patient's tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation; AND
   - **B)** Patient 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)** Patient meets one of the following criteria (i or ii):
     - **i.** There are no satisfactory alternative treatments; OR
     - **ii.** Patient has disease progression following treatment.

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]. Stamford, CT: Loxo Oncology, Inc.; November 2018.
2. The NCCN Drugs & Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 14, 2020. Search terms: larotrectinib.