

Commercial/Healthcare Exchange PA Criteria

Effective: February 6th, 2019

Prior Authorization: Vitrakvi

Products Affected: Vitrakvi (larotrectinib) oral capsules and oral solution

Covered Uses: 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.

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Presence of a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation
3. Previous therapies tried/failed

Age Restrictions: N/A

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration:

Initial: 12 months

Continuation: 3 years

Other Criteria:

Solid Tumors. Approve if the patient meets the following criteria (A, B, and C):

- A. The patient's tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation; AND
- B. The patient meets one of the following criteria (a or b):
 - a. The tumor is metastatic; OR
 - b. Surgical resection of tumor will likely result in severe morbidity; AND
- C. The patient meets one of the following criteria (a or b):
 - a. There are no satisfactory alternative treatments; OR
 - b. The patient has disease progression following treatment.

References:

1. Vitrakvi® capsules and oral solution [prescribing information]. Stamford, CT: Loxo Oncology, Inc.; November 2018.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/02/2019
2	Update	Added continuation coverage duration of 3 years	Coverage Duration	7/1/2019