

# SPECIALTY GUIDELINE MANAGEMENT

## VITRAKVI (larotrectinib)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indications

Vitrakvi is indicated for the treatment of adult and pediatric patients with solid tumors that:

1. have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation,
2. are metastatic or where surgical resection is likely to result in severe morbidity, and
3. have no satisfactory alternative treatments or that have progressed following treatment.

All other indications are considered experimental/investigational and not medically necessary.

#### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Chart documentation indicating a NTRK gene fusion status.

#### III. CRITERIA FOR INITIAL APPROVAL

##### **Solid tumors with a NTRK gene fusion**

Authorization of 12 months may be granted for treatment of solid tumors that have a NTRK gene fusion without a known acquired resistance mutation, as demonstrated by laboratory testing (e.g., next-generation sequencing [NGS] or fluorescence in situ hybridization [FISH]).

#### IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

#### V. REFERENCES

1. Vitrakvi [package insert]. Stamford, CT: Loxo Oncology, Inc.; July 2019.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed July 07, 2020.