

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 when all of the following criteria are met:

- A. The tumors 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]).
- B. The disease is metastatic or surgical resection is likely to result in severe morbidity.

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 who have not experienced disease progression or an unacceptable toxicity.

V. REFERENCES

1. Vitrakvi [package insert]. Stamford, CT: Loxo Oncology, Inc.; July 2019.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed September 12, 2019.