Reference number(s)
2799-A

Specialty Guideline Management
Vitrakvi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vitrakvi	larotrectinib

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[1]

Vitrakvi 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.

Compendial Uses[2]

Histiocytic neoplasms with NTRK gene fusion:

- Erdheim-Chester Disease (ECD)
- Langerhans Cell Histiocytosis (LCH)
- Rosai-Dorfman Disease

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

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Documentation

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

Coverage Criteria

Solid Tumors with a NTRK Gene Fusion[1,2]

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]).

Histiocytic Neoplasms[2]

Authorization of 12 months may be granted for the treatment of any of the following NTRK gene fusion-positive histiocytic neoplasm subtypes as a single agent:

- Symptomatic or relapsed/refractory Erdheim-Chester Disease (ECD)
- Langerhans Cell Histiocytosis (LCH)
- Symptomatic or relapsed/refractory Rosai-Dorfman Disease

Continuation of Therapy

NTRK gene fusion positive gastrointestinal stromal tumor (GIST)

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for NTRK gene fusion positive gastrointestinal stromal tumor (GIST) when there is no evidence of unacceptable toxicity while on the current regimen.

All Other Indications

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

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References

1. Vitrakvi [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; April 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed August 13, 2025.