UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1271-5
Program	Prior Authorization/Notification
Medication	Vitrakvi® (larotrectinib)
P&T Approval Date	1/2019, 1/2020, 1/2021, 1/2022, 1/2023
Effective Date	4/1/2023; Oxford only: 4/1/2023

1. Background:

Vitrakvi® (larotrectinib) is a kinase inhibitor 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.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Vitrakvi** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Solid Tumors</u>

1. **<u>Initial Authorization</u>**

a. **Vitrakvi** will be approved based on **all** of the following criteria:

(1) Presence of a solid tumor

-AND-

(2) Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. *ETV6-NTRK3*, *TPM3-NTRK1*, *LMNA-NTRK1*, etc.)

-AND-

(3) Disease is without a known acquired resistance mutation (e.g., TRKA G595R, G623R, G696A, F617L.).

-AND-

(4) Disease is **one** of the following:

(a) Metastatic
(b) Unresectable

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Vitrakvi** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Vitrakvi therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Vitrakvi [package insert]. Bayer HealthCare Pharmaceuticals Inc.: Whippany, NJ; March 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed November 22,2022.

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Change Control	
1/2019	New program.
1/2020	Annual review. Added general NCCN recommendations for use criteria. Updated references.
1/2021	Annual review. Removed listed solid tumor examples since list was not all inclusive. No change to coverage criteria. Updated references.
1/2022	Annual review with no change to clinical criteria. Updated resistant mutation examples to reflect package insert. Updated references.
1/2023	Annual review. Removed criteria requiring previous treatment progression or no alternative therapy based on first line recommendations per NCCN for certain cancers. Added state mandate footnote. Updated reference.