UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Vitrakvi

Program	Prior Authorization
Medication	Vitrakvi® (larotrectinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, South Carolina, Rhode Island
Issue Date	1/2019
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

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.[1]

2. Coverage Criteria:

A. <u>Solid Tumors</u>

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

   a. **Vitrakvi** will be approved based on **<u>all</u>** 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-

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(3) Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

-AND-

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

(a) Metastatic
(b) Unresectable

-AND-

(5) **One** of the following:

(a) Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy)
(b) Disease has no satisfactory alternative treatments

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.

B. NCCN Recommended Regimens

1. **Initial Authorization**

a. **Vitrakvi** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

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(1) Documentation of positive clinical response to Vitrakvi therapy **Authorization will be issued for 12 months.**

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; July 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed November 18, 2020.

Program	Prior Authorization
Change Control	
Date	Change
1/2019	New program
1/2020	Annual review. Updated references.
1/2021	Annual review. Removed listed solid tumor examples since list was not all inclusive. No change to coverage criteria. Added Additional Clinical Rules section.Updated references.

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